UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

DARLENE MATHIEU, INDIVIDUALLY AND AS NEXT OF FRIEND AND GUARDIAN OF BABY M.V.M.;

Plaintiff,

v.

MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN CORPORATION; ANDA, INC.; HENRY SCHEIN, INC.; GENERAL INJECTABLES & VACCINES, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; MYLAN PHARMACEUTICALS, INC.; MYLAN INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC. (f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC.); WATSON PHARMACEUTICALS, INC. (n/k/a ACTAVIS, INC.); ACTAVIS LLC; ACTAVIS PHARMA, INC. (f/k/a WATSON PHARMA, INC.); AMNEAL PHARMACEUTICALS, LLC; AMNEAL PHARMACEUTICALS, INC.; ALLERGAN PLC (f/k/a ACTAVIS PLC); ALLERGAN FINANCE, LLC (f/k/a ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC.); ALLERGAN SALES, LLC; ALLERGAN USA, INC.; DEPOMED, INC.; INDIVIOR, INC.; INDIVIOR SOLUTIONS INC.; CVS HEALTH CORPORATION; CVS PHARMACY, INC.; RITE AID CORPORATION; RITE AID HDQTRS. CORP.; WALGREENS BOOTS ALLIANCE, INC.; WALGREEN EASTERN CO.; WALGREEN CO.; WALMART INC. (f/k/a WAL-MART STORES, INC.); WAL-MART STORES EAST, LP; COSTCO WHOLESALE CORPORATION; And DOE 1-100, being those persons, firms,

MDL 2804

Case No. _____

JURY TRIAL DEMANDED

corporations, agents, servants and/or employees who authorized, ordered and/or committed the acts described in this Complaint and whose names when ascertained will be substituted by amendment by Plaintiff,

Defendants.

COMPLAINT

NOW COME Plaintiff, Darlene Mathieu, individually and as next of friend and guardian of Baby M.V.M., and hereby file Plaintiff's Complaint against Defendants, jointly and severally, for damages, equitable, statutory, and injunctive relief. In support thereof, Plaintiff states as follows:

I. INTRODUCTION

1. Baby M.V.M. ("Baby Plaintiff") was born dependent on opioids. Prenatal exposure to opioids causes severe withdrawal symptoms and lasting developmental impacts. The first days of Baby Plaintiff's life were spent in excruciating pain as doctors weaned the infant from opioid addiction. Baby Plaintiff will require years of treatment and counseling to deal with the effects of prenatal exposure.

2. Baby Plaintiff and Baby Plaintiff's family are victims of the opioid crisis that has ravaged the state of Alabama, causing immense suffering to those born addicted to opioids and great expense to those forced to deal with the aftermath.

3. At birth, Baby Plaintiff had Neonatal Abstinence Syndrome ("NAS"),[1] arising from his mother's dependence, oftentimes an addiction, upon opioids. Baby Plaintiff was forced

[1] The term "NAS" is defined to include additional, but medically-symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids from in utero exposure.

to endure a painful start to Baby Plaintiff's life: crying excessively, arching his back, refusing to feed, and shaking uncontrollably. NAS is a clinical diagnosis and best described as "a consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy."[2] Baby Plaintiff spent his first days in a Neonatal Intensive Care Unit ("NICU") writhing in agony as they endured detoxification and withdrawals from powerful opioids. Baby Plaintiff underwent Opioid Replacement Therapy to wean the newborn from their involuntary addiction. Such treatment, while medically necessary to save the child's life and lessen their suffering, prolong the negative health outcomes associated with their respective mother's ingestion of opioids.

4. Baby Plaintiff's mother was prescribed and/or consumed Defendants' opioids prior to and during gestation, resulting in Baby Plaintiff's mother opioid addiction and Baby Plaintiff's opioid exposure.

5. Baby Plaintiff's mother consumed opioids marketed, manufactured, distributed and/or sold by one or more of the Defendants.

6. Plaintiff brings this Complaint to compensate the Plaintiff and Baby Plaintiff, to eliminate the hazard to public health and safety caused by the opioid epidemic, and to abate the nuisance caused by Defendants' false, negligent, and unfair marketing and/or unlawful diversion of prescription opioids.

7. At all relevant times, the Defendants manufactured, packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to accurately represent the benefits and risks associated with the use of the prescription opioid drugs. The net result of this behavior was to flood the market with highly

[2] Prabhakar Kocherlakota, Neonatal Abstinence Syndrome, 134(2) Pediatrics 547, 547-48 (2014), available at http://pediatrics.aappublications.org/content/pediatrics/134/2/e547.full.pdf.

addictive, dangerous opioids, whether through the primary prescription market (including to females of child-bearing age) and the secondary market. At all times, the Defendants have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders. But for the dereliction of this legal duty, the robust secondary market for opioids could not have existed.

8. Baby Plaintiff is an individual who has suffered NAS as a result of exposure to opioids in utero. This drug exposure provides Baby Plaintiff the right to sue, through Baby Plaintiff's next of friend and guardian. Defendants have foreseeably caused damages to Plaintiff and Baby Plaintiff including the costs of neo-natal medical care, additional therapeutic, prescription drug purchases and other treatments for NAS afflicted newborns, and counseling and rehabilitation services after birth and into the future. Plaintiff and Baby Plaintiff bring this civil action for equitable and injunctive relief, compensatory damages, statutory damages, punitive damages, and any other relief allowed by the applicable law against Defendants.

II. PARTIES

9. Plaintiff Darlene Mathieu is the grandmother and guardian of Baby M.V.M. who was born in Mobile, Alabama, and was exposed in utero due to her birth mother's consumption of opioids, and diagnosed with NAS and spent considerable time suffering in the NICU where Baby M.V.M.'s withdrawal symptoms were treated by opioid replacement therapy. Darlene Mathieu is an adult resident citizen of Fairhope, Alabama.

10. Plaintiff directly and foreseeably sustained all damages alleged herein. Categories of past and continuing sustained damages include equitable relief and injunctive relief aimed at protecting Plaintiff and Baby Plaintiff from irreparable harm.

11. Plaintiff and Baby Plaintiff have suffered and continue to suffer these damages

directly. Plaintiff and Baby Plaintiff also seek the means to abate the epidemic Defendants' wrongful and/or unlawful conduct it has conducted, and continues to conduct.

12. McKesson Corporation ("**McKesson**") has its principal place of business in San Francisco, California, and is incorporated under the laws of Delaware.

13. During all relevant times, McKesson has distributed substantial amounts of prescription opioids to providers and retailers in the State of Alabama and the United States.

14. Cardinal Health, Inc. ("**Cardinal**") has its principal place of business in Ohio and is incorporated under the laws of Ohio. During all relevant times, Cardinal has distributed substantial amounts of prescription opioids to providers and retailers in the State of Alabama and the United States.

15. AmerisourceBergen Corporation ("**AmerisourceBergen**") has its principal place of business in Pennsylvania and is incorporated under the laws of Delaware. During all relevant times, AmerisourceBergen has distributed substantial amounts of prescription opioids to providers and retailers in the State of Alabama and the United States.

16. Defendant Anda, Inc. ("**Anda**"), is a Florida corporation with its principal office located in Olive Branch, Mississippi. Anda is the fourth largest distributor of generic pharmaceuticals in the United States. In October 2016, for reasons related to the sale and distribution of opioids, Defendant Teva USA acquired Anda for $500 million in cash. At all relevant times, Anda distributed prescription opioids throughout the United States, including in Alabama.

17. Defendant Henry Schein, Inc. is a Delaware corporation and is in the business of distributing, and redistributing, pharmaceutical products to consumers within Alabama. In 2015, Henry Schein reported that its sales reached a record $10.4 billion and that it had grown at a

compound annual rate of approximately 16 percent since becoming a public company in 1995. Overall, it is the world's largest provider of health care products and services to office-based dental, animal health, and medical practitioners.

18. Defendant General Injectables & Vaccines, Inc. is a Virginia corporation with its principal offices located in Bastian, Virginia. In 1998, Henry Schein Inc. acquired General Injectables & Vaccines, Inc. for an estimated $65 million dollars. As a subsidiary of Defendant Henry Schein, General Injectables & Vaccines, Inc. is owned and controlled by Defendant Henry Schein. Over a short period of time, General Injectables & Vaccines, Inc. distributed thousands of prescription pain pills into the State of Alabama and the United States.

19. Henry Schein, Inc. and General Injectables & Vaccines, Inc. are referred to herein as "**Henry Schein**".

20. McKesson, Cardinal, AmerisourceBergen, Anda, and Henry Schein are collectively referred to herein after as "**Distributor Defendants**."

21. The Distributor Defendants unlawfully and tortiously acted in concert in the distribution of opioids in Alabama in a manner calculated to conceal certain volumes of opioid products distribution, with said conduct causing or contributing to Plaintiff and Baby Plaintiff's injuries and damages.

22. Teva Pharmaceutical Industries, Ltd. ("**Teva Ltd**.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Ltd. is traded on the New York Stock Exchange (NYSE: TEVA), and is a leading drug company in the United States. Teva Ltd. operates globally, with significant business transactions in the United States.

23. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva Ltd. acquired Cephalon in October 2011, and Cephalon

Inc. became a wholly-owned subsidiary of Defendant Teva Ltd.

24. Teva Pharmaceuticals USA, Inc. ("**Teva USA**") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania, and is a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd.

25. Teva USA and Cephalon work together closely to market and sell Cephalon products in the United States. Since its acquisition of Cephalon in October 2011, Teva USA has conducted all sales and marketing activities for Cephalon in the United States, through its "specialty medicines" division. Teva USA and Cephalon, Inc. worked together to manufacture, promote, sell, and distribute opioids such as Actiq and Fentora in the United States. Teva USA holds out Actiq and Fentora as Teva products to the public. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo. Teva USA's parent company, Teva Pharmaceuticals Industries, Ltd. lists Cephalon and Teva USA's sales as its own on its financial reports, and its year-end report for 2012 -- in the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including inter alia sales of Fentora. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain. Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."

In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay a $425 million fine.

26. Teva USA also sells generic opioids in the United States, including generic opioids previously sold by Allergan plc, whose generics business Teva Ltd., Teva USA's parent company based in Israel, acquired in August 2016. Teva Ltd., Teva USA, and Cephalon are referred to herein as "**Teva**."

27. From 2000 forward, Cephalon has made thousands of payments to physicians, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, many of whom were not oncologists and did not treat cancer pain, but in fact to deceptively promote and maximize the use of opioids.

28. Defendant Watson Pharmaceuticals, Inc. ("**Watson**") is a Nevada corporation with its principal place of business in Corona, California. In 2013, it changed its name to Actavis, Inc.

29. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma Inc.) ("**Actavis Pharma**") is a Delaware corporation with its principal place of business in New Jersey.

30. Defendant Actavis LLC (f/k/a Actavis Inc.) ("**Actavis LLC**") is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Watson, Actavis Pharma and Actavis LLC are collectively referred to as "**Actavis**."

31. Defendant Teva Ltd. acquired ownership of Actavis in 2016. Prior to that transaction, Actavis was owned by Defendant Allergan PLC.

32. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, in the United States. Actavis acquired the rights to Kadian

from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

33. Actavis made thousands of payments to physicians nationwide including in Alabama, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

34. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

35. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of J&J.

36. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

37. J&J is the only company that owns over 10% of Janssen Pharmaceuticals stock. J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.

38. J&J, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. (collectively, "**Janssen**") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including Alabama.

39. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER.

40. Janssen made thousands of payments to physicians nationwide, including in Alabama, ostensibly for activities including participating on speakers' bureaus, providing

consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

41. Janssen, like many other companies, has a corporate code of conduct, which sets forth the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. Johnson & Johnson imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website *"Ethical Code for the Conduct of Research and Development,"* names only J&J and does not mention Janssen anywhere within the document. The *"Ethical Code for the Conduct of Research and Development"* posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

42. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of Johnson & Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, and sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case. J&J made payments to thousands of physicians nationwide, including in Alabama, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

43. Defendant Amneal Pharmaceuticals, LLC ("Amneal LLC") is a Delaware limited liability company with its principal offices in New Jersey. Defendant Amneal Pharmaceuticals, Inc. ("API") is a Delaware corporation with its principal place of business in New Jersey. API is the managing member of Amneal LLC and conducts and exercises full control over all activities of Amneal LLC. API and Amneal LLC are referred to herein as "**Amneal**."

44. At all relevant times, Amneal has sold prescription drugs, including opioids, in Alabama and across the United States.

45. Defendant Allergan plc (f/k/a Actavis plc) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland and its administrative headquarters and all executive officers located in Madison, New Jersey. Shares of Allergan are traded on the New York Stock Exchange (NYSE: AGN). In its most recent Form 10-K filed with the SEC, Allergan plc stated that it does business in the United States through its U.S. Specialized Therapeutics and U.S. General Medicine segments, which generated nearly 80% of the company's $15.8 billion in net revenue during the year ended December 31, 2018.

46. At all pertinent times, Actavis was part of the same corporate family as Allergan and sold and marketed opioids as part of a coordinated strategy to sell and market the branded and generic opioids of Allergan and Actavis. In October 2012, the Actavis Group was acquired by Watson Pharmaceuticals, Inc., and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. In October 2013, Actavis plc (n/k/a Allergan plc) acquired Warner Chilcott plc pursuant to a transaction agreement dated May 19, 2013. Actavis plc (n/k/a Allergan plc) was established to facilitate the business combination between Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc. Following the consummation of the October 1, 2013 acquisition, Actavis, Inc. (n/k/a Allergan Finance, LLC)

and Warner Chilcott plc became wholly-owned subsidiaries of Actavis plc (n/k/a Allergan plc). Pursuant to the transaction, each of Actavis, Inc.'s common shares were converted into one Actavis plc share. Further, Actavis plc (n/k/a Allergan plc) was the "successor issuer" to Actavis, Inc. and Warner Chilcott. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company thereafter changed its name to Allergan plc.

47. Defendant Allergan Finance, LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly-owned subsidiary of Defendant Allergan plc. In 2008, Actavis, Inc. (n/k/a Allergan Finance, LLC), acquired the opioid Kadian through its subsidiary, Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. Since 2008, Kadian's label has identified the following entities as the manufacturer or distributor of Kadian: Actavis Elizabeth LLC, Actavis Kadian LLC, Actavis Pharma, Inc., and Allergan USA, Inc. Currently, Allergan USA, Inc. is contracted with UPS SCS, Inc. to distribute Kadian on its behalf.

48. Defendant Allergan Sales, LLC is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is the current New Drug Application ("NDA") holder for Kadian, and in 2016, Allergan Sales, LLC held the Abbreviated New Drug Applications ("ANDAs") for Norco. Allergan Sales, LLC is the wholly-owned subsidiary of Allergan plc. The Norco ANDAs are currently held by Allergan Pharmaceuticals International Limited, which is incorporated in Ireland.

49. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is currently responsible for Norco and Kadian sales. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.

50. Defendant Allergan plc has, at all times, exercised control over these marketing and sales efforts and profits from the sale of its subsidiaries' products ultimately inure to its benefit, including those sales by Actavis during the period of its ownership and control by Allergan. Allergan and its associated entities are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including to Plaintiff and Baby Plaintiff.

51. Allergan PLC, Allergan Finance, LLC, Allergan Sales, LLC and Allergan USA, Inc. are collectively referred to hereinafter as "**Allergan**."

52. Defendant Depomed, Inc. ("**Depomed**") is a California corporation with its principal place of business in Newark, California. Depomed describes itself as a specialty pharmaceutical company focused on pain and other central nervous system conditions. Depomed develops, markets, and sells prescription drugs in Alabama and nationally. Depomed acquired the rights to Nucynta and Nucynta ER for $1.05 billion from Janssen pursuant to a January 15, 2015 Asset Purchase Agreement. This agreement closed on April 2, 2015.

53. Defendant Indivior, Inc. is a Delaware corporation with its principal place of business in Richmond, Virginia.

54. Defendant Indivior Solutions Inc. is a Delaware corporation with its principal offices located in Richmond, Virginia.

55. Indivior, Inc. and Indivior Solutions Inc. are collectively referred to hereinafter as "**Indivior**".

56. Indivior manufactures and distributes buprenorphine-based prescription drugs for the treatment of opioid dependence. Buprenorphine is a Schedule III drug. The company offers medication under the brand name Suboxone and sublingual tablets under the brand name

Subutex. Indivior, Inc. and Indivior Solutions Inc. are subsidiaries of Indivior, PLC, based in the United Kingdom. Indivior, Inc. was formerly known as Reckitt Benckiser Pharmaceuticals, Inc. Further, Indivior Solutions Inc. was formerly known as Reckitt Benckiser Pharmaceuticals, Solutions Inc.

57. Indivior has manufactured, distributed, supplied, and/or labeled opioids, including Buprenorphine shipped to Alabama.

58. Defendant Mylan Pharmaceuticals, Inc. is a West Virginia corporation with its principal office located in Canonsburg, Pennsylvania.

59. Defendant Mylan Inc. is a Pennsylvania corporation with its principal offices located in Canonsburg, Pennsylvania.

60. Mylan Pharmaceuticals, Inc. and Mylan Inc., are collectively referred to hereinafter as "**Mylan**". Mylan manufactures, promotes, sells, and distributes opioids in the U.S. and Alabama.

61. Teva, J&J, Amneal, Allergan, Depomed, Invidor, Cephalon, Actavis, Janssen, Mylan, and Noramco are collectively referred to hereinafter as the "**Manufacturer Defendants.**"

62. Defendant CVS Health Corporation, is a Rhode Island corporation with its principal place of business in Rhode Island.

63. Defendant CVS Pharmacy, Inc. ("CVS Pharmacy") is a Rhode Island corporation with its principal place of business in Rhode Island.

64. CVS Health Corporation and CVS Pharmacy, Inc. are collectively referred to as "**CVS**." CVS supplied, sold, and/or distributed prescription opioids throughout the United States, including Alabama.

65. Defendant Rite Aid Corporation is a Delaware corporation with its principal

offices located in Camp Hill, Pennsylvania.

66. Defendant Rite Aid Hdqtrs. Corp. is a Delaware corporation with its principal offices located in Camp Hill, Pennsylvania.

67. Together, Rite Aid Corporation and Rite Aid Hdqtrs. Corp. are referred to as "**Rite Aid**."

68. Rite Aid conducts business as a licensed wholesale distributor. Rite Aid also operates retail stores, including Alabama, that sell prescription medicines, including opioids. At all times relevant to this Complaint, Rite Aid distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Alabama.

69. Defendant Walgreens Boots Alliance, Inc., is a Delaware corporation with its principal place of business in Illinois. Defendant Walgreen Eastern Co. is a subsidiary of Walgreens Boots Alliance, Inc. that is engaged in the business of distributing pharmaceuticals, including prescription opioids. Defendant Walgreen, Co. is a subsidiary of Walgreens Boots Alliance Inc. that operates retail drug stores. Together, Walgreens Boots Alliance, Inc., Walgreen Eastern Co., and Walgreen Co. are referred to as "**Walgreens**."

70. Walgreens conducts business as a licensed wholesale distributor. At all relevant times, Walgreens has sold and continues to sell prescription opioids serving the state of Alabama and the United States.

71. Defendant Walmart Inc. (f/k/a Wal-Mart Stores, Inc.) is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

72. Defendant Wal-Mart Stores East, LP is also incorporated in Delaware. Collectively, Walmart Inc. and Wal-Mart Stores East, LP are referred to as "**Wal-Mart**."

73. Wal-Mart conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Alabama. Until 2018, Walmart Inc. also acted as a distributor of controlled substances for its pharmacies around the county, including Alabama. From 2000 to on or around May 2018, Walmart, Inc. operated at least six distrubtion centers that distributed controlled substances to its pharmaces in the United States, including Alabama.

74. Defendant Costco Wholesale Corporation ("Costco") is a Washington corporation with its principal place of business in Issaquah, Washington. During all relevant times, Costco has sold and continues to sell, in Alabama and nationwide, prescription opioids including the opioid drugs at issue in this lawsuit.

75. CVS, Rite Aid, Walgreens, Wal-Mart, and Costco are collectively referred to hereinafter as the "**National Retail Pharmacies.**"

76. Due to the tortious activities and conduct of the Distributor Defendants, the Manufacturer Defendants, and the National Retail Pharmacies, Alabama became, and is the hotbed of several "pill mills." A "pill mill" is a doctor's office, clinic, or healthcare facility that routinely for immediate and voluminous profit conspires in or participates in the prescribing or dispensing of controlled substances outside the scope of the prevailing standards of medical practice and in violation of Federal law regarding the prescribing of controlled substances.

77. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with

Defendants' actual, apparent, and/or ostensible authority.

78. The true names and capacities, whether individual, corporate, associate, or otherwise of certain vendors, distributors and/or their alter egos, sued herein as DOES 1 through 100 inclusive, are presently unknown to Plaintiff, who therefore sue these Defendants by fictitious names. Plaintiff will seek leave of this Court to amend this Complaint to show their true names and capacities when they become ascertained. Each of the Doe Defendants has taken part in and participated with, and/or aided and abetted, some or all of the other Defendants in some or all of the matters referred to herein, and therefore are liable for the same.

III. JURISDICTION AND VENUE

79. This Court has jurisdiction over this case under 28 U.S.C. § 1332(a) because, based on information and belief, complete diversity exists between Plaintiff and Baby Plaintiff and the Defendants, and because Plaintiff and Baby Plaintiff have been damaged in an amount that exceeds $75,000.00.

80. This Court has personal jurisdiction over Defendants because Cardinal has its principal place of business in Ohio and is incorporated under the laws of Ohio, and because each Defendant, has committed torts, in part or in whole, within the State of Ohio, as alleged herein, and/or voluntarily submitted to the jurisdiction of Ohio when obtaining a manufacturer, and/or pharmacy license. Moreover, Defendants have substantial contacts and business deadlings directly within Ohio by virtue of their manufacturing and marketing, distribution, dispensing, and sales of opioids made the subject of this Complaint. Therefore, Defendants have the requisite minimum contacts with Ohio necessary to constitutionally permit this Court to exercise jurisdiction.

81. Venue is proper in this Court pursuant to the Court’s Case Management Order No.

1, ECF No. 232 (April 11, 2018), which allows direct filing into MDL No. 2804, *In Re: National Prescription Opiate Litigation*, Case No. 1:17-md-02804-DAP. In the absence of direct filing, Plaintiff and Baby Plaintiff would have filed this Complaint in the U.S. District Court for the Southern District of Alabama. Plaintiff and Baby Plaintiff reserve the right to move for transfer at the conclusion of pretrial proceedings.

82. Moreover, Venue is proper pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims asserted herein arose in this District and Defendants are subject to personal jurisdiction in this District.

IV. THE OPIOID CRISIS

83. Opioid means "opium – like" and the term includes all drugs derived in whole or in part from the opium poppy. Opioids or opiates include any of various sedative narcotics containing opium or one or more of its natural or synthetic derivatives.

84. Before the Defendants launched their conspiracy and scheme to put prescription opioids in every house in America, the generally accepted standard of medical practice was that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

85. However, the past thirty years have been characterized by increased abuse and diversion of prescription drugs, including opioid medications, in the United States and Alabama.

86. Prescription opioids have now become widespread. Opioids, formerly prescribed

and used sparingly, are the most-prescribed class of drugs, with annual sales in the billions of dollars in the United States. In certain years, enough prescription opioids were sold to medicate every adult in the United States with a dose of five milligrams of hydrocodone every four hours for one month. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths.

87. Overdose mortalities in Alabama have increased sharply in recent years. From 2006 through 2014, there were over 5,000 deaths from overdoses in Alabama.[3] The number of overdose deaths climbed 82% from 2006 to 2014 in Alabama.[4]

88. In 2012, Alabama placed first in the nation for per capita opioid prescriptions with 143.8 prescriptions per 100 residents.[5] In 2016, Alabama was still the highest per capita opioid prescribing state.[6]

89. Alabama has the second-highest rate of nonmedical use of prescription pain relievers in the nation, covering one out of every nineteen Alabamians aged twelve or older.[7] Significant numbers of the residents of Alabama report drug dependence and nonmedical use of pain relievers.[8] Further, almost 91% of persons who have non-fatal overdose of opioids are prescribed opioids again within one year. One-third of all children who go into foster parent care do so because of the opioid addiction of their parent(s). Seven in ten opioid overdoses treated in an emergency room are due to the abuse of prescription opioids. Every thirty minutes in American, a baby is born with an opioid addiction.

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[3] *See* Alabama Opioid Overdose and Addiction Council, State of Alabama Opioid Action Plan, available at https://mh.alabama.gov/wp-content/uploads/2019/03/AlabamaOpioidOverdose_AddictionCouncilReport.pdf
[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] Rachel N. Lipari, Ph.D., et al., State and Substate Estimates of Nonmedical Use of Prescription Pain Relievers, National Survey on Drug Use and Health, Substance Abuse and Mental Health Services Administration (Jul. 13, 2017), https://www.samhsa.gov/data/sites/default/files/report%203187/ShortReport-3187.html
[8] *See e.g.,* Alabama Opioid Epidemic, amfAR, http://opioid.amfar.org/AL, at View Counties: Opioid Use.

90. Excessive numbers of opioids have been dispensed in Alabama. In 2015, Alabama had more opioid prescriptions than people.[9] From 2006 to 2012, there were over 1,700,000,000 prescription pain pills supplied to Alabama.[10] In 2017, 107.2 opioid prescriptions were written in Alabama for every 100 persons. This was the highest prescribing rate in the country and was almost twofold greater than the average U.S. rate of 58.7 prescriptions.[11]

91. Many residents of Alabama became addicted to prescription opioids. Addiction to prescription pain medication as the strongest risk factor for heroin and fentanyl addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin and fentanyl.

92. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.

93. The prescription opioid manufacturers and distributors, including Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or contributing to the national, state, and local opioid epidemic.

94. Many of the victims of the opioid epidemic, and certainly some of the most harmed, are babies born with Neonatal Abstinence Syndrome. NAS babies likely experience DNA changes at the cellular level, particularly in the tissues of the brain and nervous system and suffer lifelong afflictions as a result of maternal use of prescription opioid medications during

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[9] BlueCross BlueShield, Opioid Epidemic Grows as Alabama Ranks First Nationally Having More Opioid Prescriptions than People, June 29, 2017, https://www.bcbs.com/press-releases/opioid-epidemic-grows-alabama-ranks-first-nationally-having-more-opioid

[10] THE WASHINGTON POST, The Opioid Files: Drilling into the DEA's pain pill database, Jul. 21, 2019, https://www.washingtonpost.com/graphics/2019/investigations/dea-pain-pill-database/ (hereinafter "Drilling into the DEA's pain pill database").

[11] *Id.*

gestation. These patients often require extensive care because they are likely to experience lifelong mental health problems and disorders, developmental impairment and cognitive defects, and physical health limitations and disorders.

95. The impact of NAS can be life-long. Most NAS infants are immediately transferred to a neonatal intensive care unit for a period of days, weeks, or even months. NAS can also require an emergency evacuation for care to save the infant's life. Such emergency transportation costs thousands of dollars for each occurrence.

96. Many NAS infants have short-term and long-term developmental issues that prevent them from meeting basic cognitive and motor-skills milestones. Many will suffer from vision and digestive issues; some are unable to attend full days of school. These disabilities follow these children through elementary school and beyond.

97. Recently, there has been a dramatic increase in the number of fetuses that have been exposed to opioids. The number of babies born in the U.S. addicted to opioids tripled between 1999 and 2013.[12] Women are also victims of the opioid epidemic, and health care for opioid exposed mothers and their babies is a major factor in the nation's rising unreimbursed healthcare costs.

98. The number of infants born suffering from this insidious condition is staggering. The incidence of NAS in the United States grew leaps and bounds in a short period. Specifically, cases of NAS increased nationally from a rate of 1.2 per 1000 hospital births per year in 2000 to 5.8 per 1000. According to the CDC, the rate of women addicted to opioids during pregnancy quadrupled in 15 years. Currently, the best estimates are that a child with NAS is born as frequently as every 15 to 25 minutes.

[12] Incidence of Neonatal Abstinence Syndrome – 28 States, 1999-2013, CDC, *available at* https://www.cdc.gov/mmwr/volumes/65/wr/mm6531a2.htm

99. In Alabama, the number of infants with NAS doubled between 2010 and 2013.

100. The region including Alabama, Mississippi, Tennessee, and Kentucky has the highest rate of NAS in the country, with NAS occurring in 16.2 out of every 1,000 hospital births in 2012.[13] Further, the percentage of Alabama children in foster care because of parental drug abuse has risen from 11.5% in 2006 to 37% in 2016.[14]

101. The Substance Abuse Mental Health Services Administration has reported an alarming rate of pregnant women who abused opioids. Consequently, the number of babies born drug-dependent has increased hundreds of percentil, and the rates of children being placed in foster care due in part to parental drug abuse are skyrocketing — now it is almost one-third of all child removals.

102. Heroin and other opioid misuse during pregnancy are also associated with increased risks and incidence of placental abruption, preterm labor, maternal obstetric complications, maternal mortality, and fetal death. The opioid crisis caused by Defendants served to fuel an epidemic of heroin use.

103. NAS-diagnosed children are at increased risk for neuropsychological function. Research reveals that all children exposed to opioids and other drugs in utero are at a substantially higher risk for lower mental abilities and more signs of attention deficits, and that these effects will persist or worsen through adolescence.

104. Specifically, children diagnosed with NAS exhibit:

- by age 1: diminished performance on the Psychomotor Development Index, growth retardation, poor fine motor skills, short attention span, diminished intellectual performance;

[13] Amy Yurkanin, A grim and growing trend: Alabama sees increased cases of drug-dependent newborns (Sep. 29, 2015), *available at* http://www.al.com/news/index.ssf/2015/09/a grim and growing_trend alaba.html.
[14] Mary Sell, *Parental drug use putting more children in foster care,* DECATUR DAILY (Jan. 29, 2017), http://www.decaturdaily.cominews/local/parental-drug-use-putting-more-children-in-fostercare/article 957642a9-e3d5-52a3-b8d9-d881be352aab.html, citing Alabama Department of Human Resources.

- between ages 2-3: significantly lower cognitive abilities, including lower motor development, lower IQ, and poor language development;
- between ages 3-6: significant detrimental impact on self-regulation, including aggressiveness, hyperactivity, lack of concentration, lack of social inhibition, lower IQs (8-15 point difference), poor language development, and behavioral and school problems; and
- after 8.5 years: significantly greater difference in cognitive scores than at previous ages, especially in girls.

105. While the specific pathophysiological mechanism of opioid withdrawal in neonates is currently not known, several factors can affect the accumulation of opioids in the fetus. Opiate drugs have low molecular weights, are water soluble, and are lipophilic substances; hence, they are easily transferable across the placenta to the fetus. The transmission of opioids across the placenta increases as gestation increases and synthetic opiates cross the placenta more easily than semisynthetic opiates. NAS is the end result of the sudden discontinuation of prolonged fetal exposure to opioids.

106. Baby Plaintiff's mother either directly purchased and/or consumed prescription opioids from one or more Defendants in the primary market, or indirectly (but foreseeably) obtained them from other sources in the diversionary or secondary market. Baby Plaintiff suffers, and faces an increased risk of lifelong mental illness, mental impairment, and loss of mental capacity. Baby Plaintiff's entire health, use of body and mind, and life, including the minor child's ability to live normally, learn and work normally, enjoy relationships with others, and function as a valuable citizen, child, parent, income-earner, and person enjoying life, are at risk of being compromised and permanently impaired.

107. In one study, the number of newborns who had NAS and were admitted to the NICU increased by tenfold. Increases in the incidence of NAS have been reported uniformly

across community hospitals, teaching hospitals, and children's hospitals. [15]

108. The NAS epidemic and its consequences could have been, and should have been, prevented by the Defendants who control the U.S. drug distribution industry, or Defendants who dispense and/or prescribe opioids, and the Defendants who manufacture the prescription opioids. These Defendants have profited greatly by casuing and allowing Alabama to become flooded with prescription opioids.

109. The drug distribution industry is supposed to serve as a "check" in the drug delivery system, by securing and monitoring opioids at every step of the stream of commerce, protecting them from theft and misuse, and refusing to fulfill suspicious or unusual orders by downstream pharmacies, doctors, clinics, or patients. Defendants woefully failed in this duty, instead consciously ignoring known or knowable problems and data in their supply chains.

110. Defendants thus intentionally and negligently created conditions in which vast amounts of opioids have flowed freely from drug manufacturers to innocent individuals who became addicted, to opioid abusers, and even to illicit drug dealers - with distributors regularly fulfilling suspicious orders from pharmacies and clinics, who were economically incentivized to ignore "red flags" at the point of sale and before dispensing the pills.

111. Defendants' wrongful conduct has allowed billions of opioid pills to be diverted from legitimate channels of distribution into the illicit black market in quantities that have fueled the opioid epidemic in Alabama. This is characterized as "opioid diversion" and created a secondary market. Acting against their common law and statutory duties, Defendants have created an environment in which opioid diversion is rampant. As a result, unknowing patients

[15] Prabhakar Kocherlakota, *Neonatal Abstinence Syndrome,* 134(2) Pediatrics 547, 547-48 (2014), *available a*
http://pediatrics.aappublications.org/content/pediatrics/134/2/e547.full.pdf.

and unauthorized opioid users have ready access to illicit sources of diverted opioids.

112. For years, Defendants and their agents have had the ability to substantially reduce the consequences of opioid diversion, including the dramatic increase in the number of infants born with NAS. All the Defendants in this action share responsibility for perpetuating the epidemic and the exponential increase in the number of infants afflicted with NAS.

113. Defendants have foreseeably caused damages to Plaintiff and Baby Plaintiff, including the costs of neo-natal medical care, additional therapeutic, prescription drug purchases and other treatments for NAS afflicted newborns, and counseling and rehabilitation services after birth and into the future. Plaintiff and Baby Plaintiff brings this civil action seeking injunctive relief and any other relief allowed by law against the opioid drug distributors, manufacturers, and pharmacy Defendants that, by their actions and omissions, knowingly or negligently have distributed and dispensed prescription opioid drugs in a manner that foreseeably damaged, and continues to damage, Plaintiff and Baby Plaintiff.

114. The innocent Baby Plaintiff has sustained an exposure to opioids greater than that expected by members of the general population. Neonatal abstinence syndrome (NAS) is a generalized multi-system disorder that produces a constellation of symptoms in neonates, and results from abrupt discontinuation of opioids consumed by the mother during pregnancy at the infant's birth. All infants born to mothers with opioid use disorders are at high risk for developing NAS and there are no well-defined strategies to prevent NAS from occurring in at-risk infants.

115. Opioids represent a single class of exposures since they all cause their effects at the same receptors which are those that mediate the effects of endogenous opiates. Opioids represent a single class of chemical substances since their molecular structures are very similar.

Opioids have typical pharmacological effects which are common to the group: effects on the brain, the nervous system and the gastrointestinal system.

116. The opioid compounds all act at the same biological receptors and mimic natural peptides which have powerful and wide-ranging activity in living systems. Thus, they can be considered a class of chemical drugs both in terms of their pharmacological dosage activity relationships and also their overall chemical structure. They all produce addiction and dependence and cause withdrawal symptoms on removal. Their activity as modulators of neurological signaling makes them especially dangerous in adults due to rebound effects, but also they are now known to have significant effects on fetal development since they alter the cellular signaling environment.

117. The effect of all opioids is produced through a single common pathway – the opioid receptor. The opioid receptor system is ancient and highly conserved, being present by the time that jawed vertebrates first appeared at least 450 million years ago. Clearly, differences between opioid products and potency exist, but their mode of action via the opioid receptor system remains identical.

118. Fetal development relies on the balanced control of cell proliferation and cell death through apoptosis. It has been demonstrated scientifically that exposure to opiates will increase the rate of apoptotic cell death in developing biological systems. This represents a common mode of action which leads to the large plethora of adverse conditions associated with fetal opioid exposure, including – sub-optimal brain maturation, a form of functional teratogenesis associated with reduced cognitive function. Perturbed apoptosis is also a contributory factor in gross fetal malformations. These include mid-line fusion defects such as cleft palate, spina bifida and gastroschisis postnatally. Apoptosis is also essential for normal heart

development. The heart develops from a single tube into a four-chamber heart through a series of complex foldings. Such foldings are produced by cellular proliferation on one side of a tube accompanied by apoptosis on the other side, the asymmetric growth rates thus producing folding. It is clear to see that the mechanism of altered apoptosis rates leads to malformations.

119. Supportive measures are the standard of care, and pharmacotherapy is often initiated to treat their inability to sleep, lack of weight gain, inadequate caloric intake, extreme irritability, seizures and hypertonicity. If a neonate is treated with an opioid, the drug withdrawal has to be gradually tapered as the infant regains the capacity for self-regulation.

120. Buprenorphine and methadone are the most commonly used agents for opioid replacement therapy. Upon information and belief, the agents used in Opioid Replacement Therapy are manufactured and/or distributed by the Defendants, thereby creating a revenue stream not only from addicting adults who obtained opioids from the street or through a prescription but also creating a revenue stream for Defendants by treating the babies born addicted to opioids.

121. Although a widely-accepted treatment, Opioid Replacement Therapy in neonates is associated with a plethora of negative health impacts, including but not limited to reduced brain and somatic growth, intractable nystagmus, altered visual evoked potentials, delayed encephalopathy, respiratory depression, bradycardia, hypotension, urinary retention, reduced gut motility and emesis. Specifically, the widely-used Opioid Replacement Therapy agent, Buprenorphine, has been associated with extremely poor outcomes in children up to the age of 3 to whom the drug was prescribed, including congenital heart disease, urinary collecting system defects, ophthalmic defects and maxillofacial defects.

122. Major risks from prenatal opioid exposure include birth defects, altered brain

development and NAS. NAS can cause latent defects to the muscular-skeletal system, the digestive system, the cardio-vascular system and the nervous system. Evidence that opioids behaved as they were predicted to and caused major birth defects appeared in the results of the National Birth Defect Prevention Study published in 2010. The study looked at 17,449 cases and 6701 controls. Statistically Significant effects were found for associations between early pregnancy maternal opioid analgesic treatment and certain birth defects, notably heart defects, anencephaly, cleft palate and spina bifida.

123. Long-term cognitive development is impaired in children born with NAS. Further, those children face a significantly increased risk of mental, speech/language and emotional disorders. Children born with NAS face increased risk of falling prey to the disease of addiction. While much is known about the risks of serious latent disease faced by children born with NAS who underwent opioid replacement therapy, recent animal studies have revealed evidence indicating association with additional negative health outcomes: increased incidence of neural tube defects, severe heart defects, spina bifida, impaired nerve myelination, and reduced regional brain volumes in the basal ganglia.

124. The aforementioned risks of serious latent negative health impacts were not disclosed, or even mentioned, in the Defendants' marketing materials, package inserts, label warnings, unbranded research, captive advocacy group communications, or any other means of communication.

125. The Defendants purposely misrepresented that there were no teratogenic or mutagenic effect associated with the use of opioids to increase their profits.

126. The Defendants purposely misrepresented the potential of opioids to result in the negative health impacts described in this Complaint.

127. Defendants' pathway to maximizing profits were constrained by the amount of medically necessary opioids that could be sold through controlled channels. The stark reality Defendants faced in terms of maximizing profits was that they could only sell so many prescription opioids to dying cancer patients. "The logic was simple: While the number of cancer patients was not likely to increase drastically from one year to the next, if a company could expand the indications for the use of a particular drug, then it could boost sales exponentially without any real change in the country's health demography." Without a new and robust primary market, there would be no supply for the secondary "spill-over" diversionary market that they intended.

128. Once exposed, users of the opioids could easily transition into the secondary market, which was necessarily supplied from the primary market, and which Defendants were legally charged with insuring there was no supply for. Soon, the demand from the secondary market was further driving prescriptions written for the primary market.

129. Thus began the Defendants' quest to open a new primary market for opioid prescriptions: treatment of (a) chronic, (b) widespread pain (c) without dose limits. And, their "ace in the hole" was this: not only could they convince physicians to write prescriptions into this new market, they could ensure through the insidious mechanism of addiction that patients, including Alabama women of child-bearing age, like Baby Plaintiff's mom, would have to keep coming back for more. With the insidious power to create both unlimited supply and unlimited demand for these highly-addictive substances, the Defendants set out to create the new primary market. Each of the elements of the new primary market was selected to maximize sales of the highly addictive drugs. Defendants were the architects of the transition from a limited market pool of disease and injury (i.e., cancer, disorders requiring surgery, etc.) to widespread use to

treat an ever-enlarging pool of common, non-life threatening, maladies and conditions, such as arthritis, back pain, and joint pain. Thus, the universe of targeted patient conditions could be vastly expanded by Defendants.

130. Next up was Defendants' successful promotion of highly addictive opioids for chronic, i.e., long-term conditions; this step was critical to ensuring that the newly targeted patient conditions would not result in one-time sales.

131. Finally, to ensure even further sales growth and profits, Defendants promoted the notion that there were no dose limits and, indeed, that patients who appeared to be addicted were actually patients who should be given even more and higher dosages for opioids.

132. In order to maximize profits, Defendants collectively had to convince physicians to expand treatment of their patients to include chronic and "non-malignant", i.e., non-cancer, pain. And, the Defendants engaged in this activity despite the fact that the benefits of opioids are minimal in comparison to known risks, which are extreme - even fatal. Prospective, randomized, controlled trials lasting at least four weeks that evaluated the use of opioids for chronic non-cancer-related pain showed only a negligible to modest improvement in pain-relief and no consistent improvement in physical functioning. The maximal adverse risks, however, are a witches' brew known to include a "high incidence of opioid abuse behaviors" and "addiction."

133. The market innovator that "inspired" all other Defendants to follow was Purdue[16], the maker of OxyContin. It was not pharmacological innovation in which it led, but deceptive marketing, sales, and public relations innovation.[17]

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[16] Bankruptcy protection has been sought by former Defendants to this action Purdue Pharma, L.P., Purdue Pharma, Inc., and The Purdue Frederick Company. Other persons/entities related to unnamed co-conspirator Purdue include Richard S. Sackler, Jonathon D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler, Rhodes Technologies, Rhodes Technologies Inc., Rhodes Pharmaceuticals Inc., Trust for the Benefit of Members of the Raymond Sackler Family, and The P.F. Laboratories, Inc.

[17] Mike Mariani, "How the American Opiate Epidemic Was Started by One Pharmaceutical Company," *Pacific Standard*, March 4, 2015.

134. Concurrent with the innovative marketing techniques of Purdue, were the efforts of the entire industry to secure a highly potent and stable supply of the active pharmaceutical ingredient (API) in opioids. Upon information and belief, Janssen actively conspired with other Manufacturers and Distributor Defendants to significantly increase the supply of powerful opioid drugs in the market, thereby exacerbating the opioid epidemic. In a quest to dominate the growing opioid market, J&J grew poppies in Tasmania, Australia, and imported and sold APIs derived from these poppies necessary for the manufacture of opioid drugs to other Manufacturer Defendants.

135. The Defendants had an absolute and non-delegable duty to ensure that a supply of controlled substances for a secondary market did not exist. To be clear, the diversion and misuse of controlled substances is a known high-risk factor with significant negative consequences for families, communities, and even entire states.

136. In the case of prescription opiates, not only did Defendants wholly fail in that duty, but they intentionally endeavored to flood the primary market with such an excess of drugs that they either knew, or consciously and willfully disregarded the fact, that this would result in misuse and diversion into a secondary market.

137. Flooding an entire country with this many highly addictive opiates did not occur by accident. Instead, it occurred as the result of a highly coordinated, expensive, misleading, illegal, and callous manipulation of both the sales and distribution schemes for controlled substances within the United States, including Alabama.

138. As Senator McCaskill aptly recognized:

> The opioid epidemic is the direct result of a calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids

> could treat pain without risk of serious addiction. As it turns out, these messages were exaggerations at best and outright lies at worst.

139. To establish and exploit the lucrative market of chronic pain patients, each Manufacturer Defendant developed a well-funded, sophisticated, and fraudulent marketing and distribution scheme targeted at consumers and physicians. These Defendants used direct marketing, as well as veiled advertising by seemingly independent third parties, to spread misrepresentations about the risks and benefits of long-term opioid use – statements that created the "new" market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers. These statements were deceptive, false, and unfair. They were not supported by, and in fact contrary to, scientific evidence.

140. The Manufacturer Defendants spread their false, deceptive, and unfair statements by marketing their branded opioids directly to doctors and patients in Alabama. In fact, they specifically targeted susceptible prescribers and vulnerable patient populations, including those in Alabama. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false, reckless, and/or negligent statements about the risks and benefits of opioids for the treatment of chronic pain throughout geographic areas and patient demographics of Alabama.

141. The Manufacturer Defendants' direct and branded advertisements falsely portrayed the benefits of opioids for chronic pain.

142. The Manufacturer Defendants also promoted the use of opioids for chronic pain through "detailers" – sophisticated and specially trained sales representatives who visited individual doctors and medical staff and fomented small-group speaker programs. In 2014, for instance, these Defendants spent almost $200 million on "detailing" branded opioids to doctors.

143. Defendants identified doctors who were their most prolific prescribers. However, this was done not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement.

144. Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors and pill mills to target for marketing and to monitor their own and competitors' sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high-frequency detailing visits. This focus on marketing to the highest prescribers demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of

investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

145. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Manufacturer Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

146. The Manufacturer Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10

were not told opioids were potentially addictive.

147. The Manufacturer Defendants invited doctors to participate, for payment and other remuneration, on and in speakers' bureaus and programs paid for by these Defendants. These speaker programs were designed to provide incentives for doctors to prescribe opioids, including recognition and compensation for being selected as speakers. These speakers gave the false impression that they were providing unbiased and medically accurate presentations when they were, in fact, presenting a script prepared by these Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

148. The Manufacturer Defendants' detailing to doctors was highly effective in the national proliferation of prescription opioids. Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctors, allowing specific and individual targeting, customizing, and monitoring of their marketing.

149. The Manufacturer Defendants have had unified marketing plans and strategies from state to state, including in Alabama. This unified approach ensures that Defendants' messages were and are consistent and effective across all their marketing efforts.

150. The Manufacturer Defendants negligently marketed opioids in Alabama through unbranded advertising that promoted opioid use generally, yet was silent as to any specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by these Defendants and their public relations firms and agents.

151. The Manufacturer Defendants used putative third-party, unbranded advertising.

These Defendants used third-party, unbranded advertising to create the false appearance that the negligent messages came from an independent and objective source.

152. The Manufacturer Defendants' negligent unbranded marketing also contradicted their branded materials.

153. The Manufacturer Defendants marketed opioids through a small circle of doctors who were vetted, selected, funded, and promoted by these Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." These Defendants paid KOLs to serve in a number of doctor-facing and public-facing capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacture to distribution to retail.

154. The Manufacturer Defendants also entered into and/or benefitted from arrangements with seemingly unbiased and independent organizations or groups that generated treatment guidelines, unbranded materials, and programs promoting chronic opioid therapy, including the American Pain Foundation ("APF"), American Academy of Pain ("AAP"), American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), U.S. Pain Foundation ("USPF"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG").

155. Patient advocacy organizations and professional societies like these play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.

156. The Manufacturer Defendants collaborated, through the aforementioned organizations and groups, to spread false, reckless, and/or negligent messages about the risks and

benefits of long-term opioid therapy.

157. APF was the most prominent member of the seemingly independent groups the Manufacturer Defendants used and was funded almost exclusively by the Manufacturer Defendants, receiving more than $10 million in funding from the Manufacturer Defendants between 2007 and the close of its business in May 2012. APF had multiple contacts and personal relationships with the Manufacturer Defendants through its many publishing and educational programs, funded and supported by the Manufacturer Defendants. On information and belief, between 2009 and 2010, APF received more than eighty percent of its operating budget from pharmaceutical industry sources.

158. On information and belief, APF was often called upon to provide "patient representatives" for the Manufacturer Defendants' promotional activities, including for Janssen's "Let's Talk Pain." APF functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients.

159. APF is also credited with creating the PCF. On information and belief, former APF President Will Rowe described the PCF as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

160. Upon information and belief, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

161. A *ProPublica* investigation found that nearly 90% of APF's funding came from the drug and medical device community, including Manufacturer Defendants. Within days of

being investigated by a Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

162. The American Academy of Pain Medicine ("AAPM") was another group that had systematic ties and personal relationships with the Manufacturer Defendants. AAPM's corporate council includes Depomed, Teva and other pharmaceutical companies. AAPM millions of dollars in funding from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM described the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allowed drug company executives and marketing staff to meet with AAPM executive committee members in small settings. The Manufacturer Defendants were all members of the council and presented deceptive programs to doctors who attended this annual event.

163. The Manufacturer Defendants internally viewed AAPM as "industry friendly," with Defendants' advisors and speakers among its active members. The Manufacturer Defendants attended AAPM conferences, funded its CMEs and satellite symposia, and distributed its publications. AAPM conferences heavily emphasized sessions on opioids.

164. Upon information and belief, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities and publications for AAPM to pursue. AAPM then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

165. APS was another group with systematic connections and interpersonal relationships with the Manufacturer Defendants. APS was one of the groups investigated by Senators Grassley and Baucus, as evidenced by their May 8, 2012 letter arising out of their investigation of "extensive ties between companies that manufacture and market opioids and non-profit organizations" that "helped created a body of dubious information favoring opioids."

166. Upon information and belief, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities and publications for APS to pursue. APS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

167. FSMB was another group with systematic connections and interpersonal relationships with the Manufacturer Defendants. In addition to the contributions reported in *Fueling an Epidemic*, a June 8, 2012 letter submitted by FSMB to the Senate Finance Committee disclosed substantial payments from the Manufacturer Defendants beginning in 1997 and continuing through 2012. Not surprisingly, the FSMB was another one of the groups investigated by Senators Grassley and Baucus, as evidenced by their May 8, 2012 letter arising out of their investigation of "extensive ties between companies that manufacture and market opioids and non-profit organizations" that "helped created a body of dubious information favoring opioids."

168. USPF was another group with systematic connections and interpersonal relationships with the Manufacturer Defendants. The USPF was one of the largest recipients of contributions from the Manufacturer Defendants, collecting millions of dollars over multiple years. The USPF was also a critical component of the Opioid Marketing Enterprise's lobbying efforts to reduce the limits on over-prescription. USPF advertised its ties to the Manufacturer

Defendants, listing opioid manufacturers like Teva, Depomed, and McNeil (i.e., Janssen) as "Platinum," "Gold," and "Basic" corporate members. Industry groups like AAPM, AAPM, APS, and PhRMA are also members of varying levels in the USPF.

169. AGS was another group with systematic connections and interpersonal relationships with the Defendants. AGS was a large recipient of contributions from the Manufacturer Defendants, including Janssen. AGS contracted with the Manufacturer Defendants to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (The Management of Persistent Pain in Older Persons) and 2009 (Pharmacological Management of Persistent Pain in Older Persons). According to news reports, AGS has received funding from opioid manufacturers for many years. AGS internal discussions in August 2009 reveal that it did not want to receive upfront funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

170. Upon information and belief, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

171. The Defendants also had systematic links to and personal associations with each other through their participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities, including but not limited to, the Pain Care Forum ("PCF") and the Healthcare Distribution Alliance ("HDA").

172. The PCF has been described as a coalition of drugmakers, trade groups and

dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF, including the Manufacturer Defendants, quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

173. PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.

174. Not surprisingly, each of the Manufacturer Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.

175. In 2012, membership and participating organizations in the PCF included the HDA (of which all the Manufacturer Defendants are members), Johnson & Johnson, and Teva. AAPM, APF, and APS were also members of the PCF.

176. The HDA is an industry trade association for wholesalers and distributors. The benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."

177. The HDA also offered multiple conferences, including annual business and leadership conferences through which the Manufacturer Defendants had an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."

178. The Defendants met regularly and conspired through the artifice of the PCF and HDA.

179. To convince doctors and patients in Alabama that opioids can and should be used

to treat chronic pain, these Defendants had to persuade them that long-term opioid use was both safe and helpful. Knowing that they could do so only by misrepresenting the risks and benefits of long-term opioid use to those doctors and patients, these Defendants made claims that were not supported by or were contrary to the scientific evidence and which were contradicted by data.

180. To convince doctors and patients that opioids are safe, the Manufacturer Defendants negligently trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (a) starting patients on opioids was low- risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (b) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, but they continue to make them today.

181. The Manufacturer Defendants falsely claimed that the risk of opioid addiction is low and that addiction is unlikely to develop when opioids are prescribed (as opposed to obtained illicitly), and failed to disclose the greater risk of addiction with prolonged use of opioids. Some examples of these misrepresentations by opioid manufacturers contrary to the science are:

a. Actavis employed a patient education brochure that claimed opioid addiction is "less likely if you have never had an addiction problem";

b. Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain, claiming that addiction is rare and limited to extreme cases of unauthorized doses;

c. Janssen distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults which described as "myth" the claim that opioids are addictive;

d. a Janssen website claimed that concerns about opioid addiction are "overestimated";

e. Depomed's Senior Vice President and Chief Financial Officer, August Moretti, told investors that "[a]lthough not in the label, there's a very low abuse profile and side effect rate" for Nucynta; and

f. Janssen's unbranded website "Prescribe Responsibly" stated that concerns about addiction were "overestimated" and that "true addiction occurs only in a small percentage of patients."

182. The Manufacturer Defendants negligently instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudo-addiction" – a term used by Dr. David Haddox, and Dr. Russell Portenoy, KOLs for Cephalon and Janssen. Defendants negligently claimed that pseudo-addiction was substantiated by scientific evidence. Some examples of these negligent claims are: (a) Cephalon sponsored Responsible Opioid Prescribing, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudo-addiction, rather than true addiction; (b) Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudo- addiction . . . refers to patient behaviors that may occur when pain is under-treated."

183. The Manufacturer Defendants recklessly and/or negligently instructed doctors and patients that addiction risk screening tools, patient agreements, urine drug screens, and similar strategies were very effective to identify and safely prescribe opioids to even those patients predisposed to addiction. These misrepresentations were reckless because Manufacturer Defendants directed them to general practitioners and family doctors who lack the time and

expertise to closely manage higher-risk patients on opioids. Manufacturer Defendants' misrepresentations were intended to make doctors more comfortable in prescribing opioids. Some examples of these claims are: Cephalon sponsored a continuing medical education ("CME") presentation offered by Medscape in 2003 entitled Pharmacologic Management of Breakthrough or Incident Pain that taught that "[c]linicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse" and "[t]he concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse."

184. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Manufacturer Defendants falsely claimed that opioid dependence can easily be solved by tapering, that opioid withdrawal was not difficult, and that there were no problems in stopping opioids after long-term use.

185. Manufacturer Defendants negligently minimized the significant symptoms of opioid withdrawal – which include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use. The Manufacturer Defendants negligently claimed that doctors and patients could increase opioid dosages indefinitely without added risk of addiction and other health consequences and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and

lower dosages did not provide pain relief. For example: (a) an Actavis patient brochure stated - "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction;" (b) Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain, claiming that some patients need larger doses of opioids, with "no ceiling dose" for appropriate treatment of severe, chronic pain; and (c) a Janssen patient education guide Finding Relief: Pain Management for Older Adults listed dosage limitations as "disadvantages" of other pain medicines yet omitted any discussion of risks of increased opioid dosages.

186. Manufacturer Defendants' marketing of the so-called abuse-deterrent properties of some of their opioids created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

187. Manufacturer Defendants have made misleading claims about the ability of so-called abuse-deterrent opioid formulations to deter abuse, yet knowing full well that these formulations were evidence of voluminous misuse of the pills.

188. These numerous, longstanding misrepresentations minimizing the risks of long-term opioid use persuaded doctors and patients to discount or ignore the true risks. Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. Despite this, Defendants negligently and misleadingly touted the benefits of long-term opioid use and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false claims, they continue to make them today.

189. For example, the Manufacturer Defendants falsely and recklessly, and/or negligently claimed that long-term opioid use improved patients' function and quality of life,

including the following misrepresentations: (a) an Actavis advertisement claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives; (b) a Janssen patient education guide Finding Relief: Pain Management for Older Adults stated as "a fact" that "opioids may make it easier for people to live normally" such as sleeping peacefully, working, recreating, having sex, walking, and climbing stairs; (c) Responsible Opioid Prescribing, by Cephalon, taught that relief of pain by opioids, by itself, improved patients' function; (d) Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain, which counseled patients that opioids "give [pain patients] a quality of life we deserve"; (e) Janssen sponsored, funded, and edited a website, Let's Talk Pain, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function"; and (f) Cephalon's and Janssen's sales representatives conveyed the message that opioids will improve patient function.

190. The Manufacturer Defendants also negligently and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, APF's A Policymaker's Guide to Understanding Pain & Its Management, sponsored by Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months" and (falsely) attributed 10,000 to 20,000 deaths annually to NSAID overdose, with no corresponding warning for opioids.

191. Once again, these misrepresentations by Defendants contravene pronouncements based on the scientific evidence. Each Manufacturer Defendant has fraudulently, recklessly, and negligently marketed its opioids on numerous occasions.

192. Cephalon negligently marketed its opioids Actiq and Fentora for chronic pain even though their uses have expressly been limited to the treatment of cancer pain in opioid-

tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

193. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009, instructing doctors that "clinically, broad classification of pain syndromes as either cancer or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain;

b. Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and

c. In December 2011, Cephalon widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals – that

openly promotes Fentora for "multiple causes of pain" and not just cancer pain.

194. Cephalon's marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

195. In summary, Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudo-addiction, even for high-risk patients;

c. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic, non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

d. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including inpatient education materials, concerning the use of opioids to treat chronic, non-cancer pain;

e. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic, non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

g. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of medical providers, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

h. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic, non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

i. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

196. In Alabama, Actavis is engaged in the manufacture, promotion, distribution, and sale of opioids such as the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

197. Actavis negligently promoted Kadian through its detailers and direct-to-physician marketing. In 2010, an FDA-mandated "Dear Doctor" letter required Actavis to inform doctors that "Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

198. In summary, Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic, non-cancer pain and that opioids improve quality of life;

c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic, non-cancer pain and that opioids improve quality of life while concealing contrary data.

199. Depomed sales representatives misrepresented the safety and efficacy of its opioid drugs to physicians. Depomed has, since at least October 2011, engaged in unsafe and/or

unapproved marketing of Lazanda and (with the acquisition from Janssen in January 2015) of Nucynta and Nucynta ER. Depomed sales representatives promoted Lazanda for unsafe and unapproved uses.

200. Lazanda is only indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." Despite the drug's explicit limitation, Depomed actively promoted Lazanda to physicians who do not treat cancer patients. Not only did Depomed instruct sales representatives to promote Lazanda to non-cancer treating physicians, the Depomed also discouraged sales representatives from marketing the drug to physicians treating cancer patients, even if the sales representatives were successful in gaining these doctors' business.

201. When it launched Lazanda, the Company's management, from the start, disregarded the FDA's limitations concerning Lazanda's usage, instructing its sales representatives to target pain management physicians, particularly those who historically wrote large numbers of ROOs and Lazanda-like drugs.

202. Sales representatives were pressured to target pain management physicians. Area managers at Depomed regularly supplied sales representatives with lists of target physicians containing few, if any, physicians treating cancer patients. Of the typical call list containing approximately 100 physicians, under five generally treated cancer patients.

203. Depomed also strongly discouraged sales representatives from targeting physicians treating cancer patients. Sales representatives had to "make a case" for using any portion of their allotted marketing money to call on cancer treating physicians. And employees who did call on cancer treating physicians were disciplined.

204. One Depomed sales representative, who worked in the Los Angeles area, was chastised by management for targeting, almost exclusively, physicians treating cancer patients despite the fact that he had been very successful in generating business from these physicians. This representative was reprimanded for targeting physicians who could prescribe Lazanda for its indicated use, and was told to stop targeting these physicians, and to think about how well he could be doing if he was targeting potentially higher writers. Depomed explicitly told sales representatives to market only to non-cancer treating physicians by their managers, most notably Todd Wittenbach, the company's then head of sales for the United States.

205. Depomed sales representatives were also trained to deal with pushback from physicians. For example, when confronted with the common statement from a physician that "it's extremely rare that we see cancer patients," Depomed trained sales representatives to divert the conversation to the physician's use of other, similar medications. For example, sales representatives were trained to respond by saying "well tell me about your patients taking Actiq," and then extol the relative benefits of switching those patients to Lazanda.

206. Due to the worsening headwinds within the opioid market, Depomed ultimately sold Lazanda to Slán Medicinal Holdings. Depomed sales representatives also promoted Nucynta and Nucynta ER for unsafe and unapproved uses.

207. Depomed acquired from Janssen and its affiliates the U.S. rights to the Nucynta franchise of pharmaceutical products for $1.05 billion in cash. The Nucynta franchise is an opioid that includes Nucynta ER (tapentadol) extended-release tablets indicated for the management of pain, including neuropathic pain associated with diabetic peripheral neuropathy (DPN), severe enough to require daily, around-the-clock, long-term opioid treatment, Nucynta IR (tapentadol), an immediate release version of tapentadol, for management of moderate to severe

acute pain in adults, and Nucynta (tapentadol) oral solution, an approved oral form of tapentadol that has not been commercialized.

208. The marketing strategy causing the astronomical growth in sales, however, was fueled by Depomed's illegal practices in connection with its marketing of Nucynta for unsafe and unapproved uses. In particular, Depomed promoted the use of opioids for all manner of pain management while downplaying the drug's addictive nature, often promoting the drug as a safer alternative to opioids.

209. Further, Depomed promoted an increase in dosage while focusing on family physicians and internal medicine doctors who were less knowledgeable about the dangers of opioids. In February 2017, Depomed's former CEO increased its sales force for the specific purpose of targeting primary care physicians.

210. Depomed's marketing push was "Think Differently." Sales representatives were told that Nucynta is a "safer opioid." They were told to tell physicians about Nucynta and its value to patients in terms of, among other things, improved safety relative to other opioids on the market.

211. Depomed actively targeted primary care physicians with marketing presentations that described Nucynta as a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids. Depomed did not have approval to market Nucynta in this manner, and also did not have any independent scientific evidence to support these claims.

212. The approved labels for both Nucynta IR and Nucynta ER describe the tapentadol molecule as "a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone." Nowhere on the approved label does it say or mention that Nucynta is safer, more tolerable, less

abusive, or less addictive than other opioids. Despite this, Nucynta has a long history of its manufacturer (formerly Janssen) claiming these benefits in its sales pitches and marketing.

213. Nonetheless, Depomed directed its sales representatives to market Nucynta for unsafe and unapproved uses as a safer, less abusive, less addictive opioid that did not create the same euphoric feeling as other opioids, even though this was not on the approved label.

214. Depomed management knew that the approved label for Nucynta contained no information about it being safer, more tolerable, less addictive, or less abusive than alternative opioids, and knew they could not market Nucynta this way.

215. On an investor call, August Moretti, Depomed's Senior Vice President and Chief Financial Officer, stated that "[a]lthough not in the label, there's a very low abuse profile and side effect rate."

216. In a presentation at the ROTH Conference, then Depomed CEO Schoeneck stated: "The addiction profile is thought to be better. I can't make a claim around that because we don't actually have that in the label." In February 2017, Schoeneck also told investors that Depomed was "initiating label enhancement studies, aimed at further differentiating Nucynta by highlighting its respiratory depression and abuse potential profile. These labeling studies will focus on the properties of the tapentadol molecule, and its uniqueness in the pain marketplace." The purpose of this was to "be able to get it hopefully into the label."

217. Depomed represented that Nucynta was uniquely positioned to combat the negative public sentiment against opioids. Former President and CEO James Schoeneck described to investors that Nucynta had "different properties than the other opioids, particularly when it comes to the kind of activity that the CDC and others are most concerned about" and that "there'll be relatively little impact on [Depomed] compared to where some other companies may

fall in at."

218. Depomed knew that it could not promote Nucynta as a safer, less addictive, less abusive opioid that did not have the same euphoric feeling on patients because these properties were not on its approved label. Despite this knowledge, Depomed trained its sales representatives to use these marketing tactics to sell Nucynta, using the same sales team as Janssen had to promote Nucynta, knowing that Janssen was being sued for, among other things, improperly marketing Nucynta.

219. Due to the worsening headwinds within the Opioid market, Depomed ultimately entered into a commercialization agreement with Collegium Pharmaceutical, Inc., for the NUCYNTA brand.

220. For decades, the Johnson & Johnson Defendants (hereinafter referred to "J&J"), Johnson & Johnson, Janssen and Normaco, developed, produced marketed, promoted, and sold opioid drugs and the ingredients for opioid drugs across the nation. Although changes in corporate structure and ownership evolved during the Opioid Crisis, the Johnson & Johnson Defendants independently and in concert contributed to the public nuisance created by their tortious acts.

221. Noramco was a wholly-owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital. All allegations pertaining to J&J also apply to Noramco. Moreover, Noramco is a Manufacturer Defendant, and all allegations against the Manufacturer Defendants herein apply equally to Noramco.

222. Janssen is a wholly owned subsidiary of J&J and its manufacturer of opioid drugs. All allegations pertaining to J&J also apply to Noramco. Moreover, Noramco is a Manufacturer

Defendant, and all allegations against the Manufacturer Defendants herein apply equally to Noramco.

223. Janssen disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic, non-cancer pain and that opioids improve quality of life, while concealing contrary data;

c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudo-addiction through internet sites over which Janssen exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

f. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic, non-cancer pain and misrepresented the risks of opioid addiction in this population;

g. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic, non-cancer pain and improve quality of life, while concealing contrary data;

h. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic, non-cancer pain;

i. Directly distributing and assisting in the dissemination of literature written that contained deceptive statements concerning the use of opioids to treat chronic, non- cancer pain, including the concept of pseudo-addiction;

j. Creating, endorsing, and supporting the distribution of patient and prescriber

education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic, non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

k. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic, non-cancer pain; and

l. Making deceptive statements concerning the use of opioids to treat chronic, non-cancer pain to prescribers through in-person detailing.

224. Moreover, as part of its marketing, promotion, and sale of opioid drugs, J&J specifically manufactured and sold opioid drugs through Janssen as part of its pain franchise, including (i) Duragesic transdermal patch made out of the active pharmaceutical ingredient ("API") fentanyl; (ii) Ultram and Ultram Extended Release ("ER") tablets made out of the APIs tramadol and acetaminophen; (iii)Ultracet – tablets made out of the APIs, tramadol and acetaminophen; (iv) Nucynta and Nucynta ER – tablets made out of the API, tapentadol; (v) Tylenol with Codeine-tablets made out of the APIs, acetaminophen and codeine; (vi) Tylox-capsules made out of the APIs acetaminophen and oxycodone.

225. Dr. Paul Janssen, the founder of Janssen Pharmaceutica, now a subsidiary of J&J, originally invented fentanyl in the 1950s. Fentanyl, an extremely powerful opioid, is a major factor in the opioid crisis, related to rising numbers of overdose deaths as well as the increasing prevalence of NAS.

226. Janssen's opioid marketing, in its multitude of forms, was false, deceptive, and misleading. These marketing activities targeted both the public at large as well as physicians and the medical community directly.

227. Additionally, misinformation from Janssen's direct marketing to doctors influenced the medical community's prescribing practices and perception of the dangers of

opioids, and encouraged doctors liberally and aggressively write a higher number of opioid prescriptions. The rapid increase in the prescribing and sale of opioid drugs is directly and causally linked to negative consequences of the opioid epidemic, including addiction and overdose deaths as well as rising rates of NAS and children entering the child welfare system.

228. Upon information and belief, Janssen actively conspired with other manufacturer and distributor defendants to significantly increase the supply of powerful opioid drugs in the market, thereby exacerbating the opioid epidemic.

229. In a quest to dominate the growing opioid market, J&J grew poppies in Tasmania, Australia and imported and sold APIs derived from these poppies necessary for the manufacture of opioid drugs to other manufacturer defendants.

230. Beginning in 1990 and continuing unabated, J&J used two of its wholly-owned subsidiaries, Noramco and Tasmanian Alkaloids Limited ("Tasmanian Alkaloids"), to pump up the supply of opioids by selling to opioid manufacturers the raw ingredients necessary to meet the growing demand for powerful opioid drugs as the opioid epidemic increased in severity. J&J had the unique information of how vast, growing, and profitable the end-to-end, cradle-to-grave opioid business was.

231. As the opioid crisis worsened, Tasmanian Alkaloids engaged in the cultivation, breeding, and processing of opium poppy plants into compounds necessary for the production of opioid APIs in Tasmania. These raw ingredients were then imported to the United States by Noramco.

232. Noramco imported the raw ingredients produced by Tasmanian Alkaloids to the United States, processed the raw ingredients into opioid APIs, and sold these APIs to opioid manufacturers.

233. Upon information and belief, J&J's activities in the production of raw opioid APIs included the development of the Norman Poppy, a strain of the plant containing high levels of the compound Thebaine, which is a critical ingredient for the production of oxycodone, oxymorphone, nalbuphine, naloxone, naltrexone, and buprenorphine.

234. Upon information and belief, the high-Thebaine Norman Poppy was patented by Tasmanian Alkaloids in 1994 and "was a transformational technology that enabled the growth of oxycodone".

235. Upon information and belief, Noramco sold opioid APIs to various other opioid manufacturers, including Teva and "all seven of the top US generic companies" through "long-term agreements."

236. Upon information and belief, when J&J transferred Noramco and Tasmanian Alkaloids to a private investment firm, Noramco was one of the nation's top suppliers of opioid APIs. In a 2015 presentation to potential buyers of the company, Noramco was described to potential buyers as the "#1 supplier of Narcotic APIs in the United States, the world's largest market."

237. Upon information and belief, J&J's supplying of raw opioid ingredients enabled manufacturer defendants to meet the growing demand for powerful and dangerous opioid drugs formed in the wake of the pharmaceutical industry's misleading mass marketing of opioid drugs to the medical community and directly to the public. By enabling the large-scale manufacture of these drugs, J&J conspired to create an opioid epidemic, addicting millions of Americans to opioid drugs and significantly increasing instances of NAS in the U.S.

238. Indivior manufactures and distributes buprenorphine-based prescription drugs for treatment of opioid dependence. Buprenorphine is a Schedule III drug. The company offers

medication under the brand name Suboxone and sublingual tablets under the brand name Subutex. Indivior has manufactured and/or labeled Buprenorphine shipped to Alabama. Indivior is a Manufacturer Defendant, and all allegations against the Manufacturer Defendants herein apply equally to Indivior.

239. As demonstrated by the allegations above, the Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and negligent. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned these Defendants of this, and these Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.

240. The Manufacturer Defendants' fraudulent, reckless, and negligent marketing scheme caused and continues to cause doctors in Alabama to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent these Defendants' negligent marketing scheme, these doctors would not have prescribed as many opioids. These Defendants' negligent marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent these Defendants' negligent marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

241. The Manufacturer Defendants' fraudulent, reckless, and negligent marketing has

caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their negligent marketing scheme. Defendants' spending on opioid marketing totaled upwards of a billion dollars.

242. The escalating number of opioid prescriptions written by doctors who were deceived by the Manufacturer Defendants' marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Alabama. In August 2016, the U.S. Surgeon General published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to negligent marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."

243. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

244. Contrary to the Manufacturer Defendants' misrepresentations, most opioid addiction begins with legitimately prescribed opioids, and therefore could have been prevented had Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got started on them through friends or relatives. Numerous doctors and

substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

245. At all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their negligent marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their own role in the negligent marketing of chronic opioid therapy by funding and working through third parties like professional societies and KOLs. These Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and negligent statements about the risks and benefits of long-term opioid use for chronic pain.

246. The Manufacturer Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. These Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, fake independent groups, and public relations companies that were not, and have not yet become, public. Manufacturer Defendants, such as Janssen, ran similar websites that masked their own direct role.

247. The Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. These Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for these Defendants' negligent messages was not apparent to medical professionals who relied upon them in making treatment decisions.

248. Thus, the Manufacturer Defendants successfully concealed from the medical community and patients facts sufficient to arouse suspicion of the claims that Plaintiff and Baby Plaintiff now assert. Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

249. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distribution companies, including Defendants Cardinal, McKesson, and AmerisourceBergen, which together account for 85-90% of all revenues from drug distribution in the United States – estimated at over a trillion dollars. The distributors then supply opioids to pharmacies, doctors, and other healthcare providers, or even other distributors or wholesalers, who then dispense the drugs to patients.

250. Manufacturer Defendants and Distributor Defendants share the responsibility for controlling the availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use, to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain.

251. For example, at the wholesale level of distribution, diversion occurs whenever distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency and duration.

252. Diversion occurs through the use of stolen or forged prescriptions at pharmacies, or the sale of opioids without prescriptions, including patients seeking prescription opioids under false pretenses.

253. Diversion occurs when manufacturers and/or distributors use other distributors or channels to put opioids into localities where otherwise a "red flag" would arise if the Defendants' distribution subterfuge had not occurred.

254. Opioid diversion occurs in the United States at an alarming rate. In recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

255. Every year, thousands of people in Alabama misuse and abuse opioid pain relievers that can lead to addiction, NAS, overdose and death. Within the last 20 years, the abuse of prescription narcotic pain relievers has emerged as a public health crisis in Alabama.

256. The dramatic rise in heroin use in recent years is a direct result of prescription opioid diversion. The strongest risk factor for a heroin use disorder is prescription opioid use. The CDC has reported that people who are dependent on prescription opioid painkillers are 40 times more likely to become dependent on heroin.

257. Plaintiff and Baby Plaintiff have been significantly damaged by the effects of the Distributor Defendants' opioid diversion efforts, schemes, artifices, failures, negligence, concealment, and misrepresentations.

258. Distributor Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise

reasonable care to prevent the threatened harm.

259. All opioid distributors are required to maintain effective controls against opioid diversion. They are also required to create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

260. For years the Distributor Defendants have known of the problems and consequences of opioid diversion in the supply chain and have committed repeated violations of laws and regulations, as alleged herein.

261. To combat the problem of opioid diversion, the DEA has provided guidance to Defendant Distributors on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions. The DEA has conducted briefings with Distributor Defendants regarding their downstream customer sales, due diligence responsibilities, and legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders to the DEA). The DEA provided Distributor Defendants with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The Distributor Defendants were given case studies, legal findings against other registrants, and the DEA's Automation of Reports and Consolidation Orders System ("ARCOS") profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA emphasized the "red flags" to identify potential diversion.

262. The DEA Office of Diversion Control sent letters to all registered distributors, including the Distributor Defendants, providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion. These letters reminded registrants that they were required by law to exercise due diligence to avoid filling orders that could be diverted into the illicit market. The DEA explained that as part of the legal obligation to maintain effective controls against diversion, the distributor was required to exercise due care in confirming the legitimacy of each and every order prior to filling. It also described circumstances that could be indicative of diversion including ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; disproportionate ratio of ordering controlled substances versus non-controlled prescription drugs; the ordering of excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors.

263. The HDMA, the Distributor Defendants' own industry group, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," emphasizing the critical role of each member of the supply chain in distributing controlled substances. These industry guidelines stated: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

264. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

265. For example, a Cardinal executive claimed that Cardinal uses "advanced analytics" to monitor its supply chain. He further extolled that Cardinal was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity" (emphasis added).

266. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our Country."

267. These assurances of identifying and eliminating criminal activity and curbing the opioid epidemic, on their face, create a duty for the Distributor Defendants to take reasonable measures to do just that.

268. In addition to the obligations imposed by law, through their own words, representations, and actions, the Distributor Defendants have voluntarily undertaken a duty to protect the public at large against diversion from their supply chains, and to curb the opioid epidemic. In this voluntary undertaking, the Distributor Defendants have miserably and negligently failed.

269. The Distributors Defendants have knowingly or negligently allowed diversion.

270. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In December 2016, a Department of Justice press release announced a multi-million dollar settlement with Cardinal. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to certain pharmacies.

271. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a $13.25 million fine. McKesson also was supposed to implement tougher controls regarding opioid diversion. McKesson utterly failed. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer. In 2015, McKesson was in the middle of allegations concerning its "suspicious order reporting practices for controlled substances." In early 2017, it was reported that McKesson agreed to pay $150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.

272. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

273. Relying on state laws and regulations, various state boards of pharmacy have directly disciplined the wholesale distributors of prescription opioids for failure to prevent

diversion, a duty recognized under state laws and regulations.

274. Although distributors, including some Distributor Defendants, have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit. The Distributor Defendants have the ability and owe the duty to prevent opioid diversion, which presented a known or foreseeable risk of damage to Plaintiff and Baby Plaintiff.

275. The Distributor Defendants have supplied massive quantities of prescription opioids in Alabama with the actual or constructive knowledge that the opioids were ultimately being consumed by citizens for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or intentionally failed to do so.

276. Each Distributor Defendant knew or should have known that the amount of the opioids that it allowed to flow into Alabama was far in excess of what could be consumed for medically-necessary purposes in the relevant communities (especially given that each Distributor Defendant knew it was not the only opioid distributor servicing those communities).

277. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in Alabama;

providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

278. On information and belief, the Distributor Defendants made little to no effort to visit the pharmacies servicing patients and citizens of Alabama to perform due diligence inspections to ensure that the controlled substances the Distributors Defendants had furnished were not being diverted to illegal uses.

279. On information and belief, the compensation the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing the patients and citizens of Alabama, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

280. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the consumer market of Alabama with highly-addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

281. It is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including neo-natal addiction and NAS.

282. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

283. The Distributor Defendants knew or should have known that a substantial amount

of the opioids dispensed to patients and citizens of Alabama were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm to individual pharmacy customers, third-parties, Plaintiff and Baby Plaintiff.

284. The Distributor Defendants were aware of widespread prescription opioid abuse of persons who would become patients in Alabama, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas – and in such quantities, and with such frequency – that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

285. The Distributor Defendants could and should have taken action that: (a) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (b) reduced the dispensing of stronger and extended-release opioids; (c) enhanced pharmacist counseling for new opioid patients; (d) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (e) required the use of immediate- release formulations of opioids before extended-release opioids are dispensed.

286. Having knowledge and/or notice of the damages that their conduct had caused to Plaintiff and Baby Plaintiff, the Distributor Defendants failed to take other steps to help curb the damages already incurred by Plaintiff and Baby Plaintiff. The Distributor Defendants could have: (a) donated medication disposal units to community police departments across the country to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to whom the prescription was not written or otherwise diverted or abused; (b) implemented a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients

may have; (c) run public education campaigns; (d) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (e) reduced the dispensing of stronger and extended-release opioids; (f) enhanced pharmacist counseling for new opioid patients; (g) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (h) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

287. The Distributor Defendants could have and should have implemented these measures at any point in the last 20 years. If any of the Distributor Defendants adhered to effective controls to guard against diversion, Plaintiff and Baby Plaintiff would have avoided significant damages. The failure to take action was negligent and did result in significant damages to Plaintiff and Baby Plaintiff.

288. The Distributor Defendants made substantial profits over the years based on the diversion of opioids affecting Alabama. Their participation and cooperation in a common enterprise has foreseeably caused damages to Plaintiff and Baby Plaintiff. The Distributor Defendants knew full well that Plaintiff and Baby Plaintiff would be unjustly forced to bear these injuries and damages.

289. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to communities showed an intentional or reckless disregard for Plaintiff and Baby Plaintiff. Their conduct poses a continuing economic threat to the communities that must deal with ongoing needs of children afflicted with NAS.

290. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids. They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into

communities, they continued to participate in the oversupply and profit from it. Each of the National Retail Pharmacies does substantial business in Alabama. This business includes the distribution and dispensing of prescription opioids.

291. Data shows that the National Retail Pharmacies distributed and dispensed substantial quantities of prescription opioids, including fentanyl, hydrocodone, and oxycodone in Alabama. In addition, they distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to Alabama. The National Retail Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it, and contributed substantially to the diversion problem.

292. The National Retail Pharmacies developed and maintained extensive data on opioids they distributed and dispensed. Through this data, National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in Alabama in particular. They used the data to evaluate their own sales activities and workforce. On information and belief, the National Retail Pharmacies also provided Defendants with data regarding, inter alia, individual doctors in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a valuable resource that they could have used to help stop diversion but failed to do so.

293. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

294. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under the Alabama Uniform Controlled Substances Act ("AUCSA"). AL. Code § 20-2-1 et seq. (1975). Because pharmacies themselves are registrants under the AUCSA, the duty

to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

295. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

296. Suspicious pharmacy orders include orders unusually large in size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

297. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

298. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing. According to industry standards, if a pharmacy finds evidence of prescription

diversion, the State of Alabama Board of Pharmacy and DEA must be contacted.

299. Despite their legal obligations as registrants under state law, the National Retail Pharmacies allowed widespread diversion to occur -- and they did so knowingly. They knew they made money by filling prescriptions, not by not filling descriptions. They knew they made money by making it easy for doctors to refer patients with drug prescriptions to them to fill, not by making it difficult for doctors to refer patients to them to fill prescriptions.

300. Performance metrics and prescription quotas adopted by the National Retail Pharmacies for their retail stores contributed to their failure. For instance, under CVS's Metrics System, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of National Retail Pharmacies and into communities throughout the country. The policies remained in place even as the epidemic raged.

301. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff and Baby Plaintiff allege that this problem was compounded by the National Retail Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

302. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff and Baby Plaintiff allege that the National Retail Pharmacies also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

303. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff and Baby Plaintiff allege that the National Retail Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

304. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff and Baby Plaintiff allege that the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

305. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff and Baby Plaintiff allege that the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

306. The National Retail Pharmacies were, or should have been, fully aware that the

quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

307. The National Retail Pharmacies have long been on notice of their failure to abide by the law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff and Baby Plaintiff allege that based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacies.

308. CVS conducts business as a licensed wholesale pharmacy and opioid distributor. CVS also operates retail stores, including in Alabama, that sell prescription medicines, including opioids. At all times relevant to this Complaint, CVS distributed prescription opioids and engaged in the retail selling and distrbution of opioids throughout the United States, including in Alabama.

309. CVS is a repeat opioids seller and distributor offender, ignoring not only red flag diversions but ignoring stop signs. CVS has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the United States Department of Justice ("DOJ"). It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require.

310. As recently as July 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies

failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances. This fine was preceded by numerous others throughout the country. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

311. In 2013, CVS was fined $350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area. In 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired. In 2015, CVS agreed to pay a $22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."

312. CVS has had knowledge and/or notice of the illicit opioid diversion and opioid addiction since at least 2002. At any time since CVS had knowledge and/or notice of the opioid problem it could have unilaterally taken steps to curtail and prevent expansion of the problem, but it failed to do so. In their capacity as wholesale pharmacy and distributors, CVS and its subsidiaries are National Retail Pharmacy Defendants, and all allegations against the National Retail Pharmacy Defendants herein apply equally to CVS.

313. Rite Aid conducts business as a licensed wholesale pharmacy and distributor. Rite-Aid also operates retail stores, including in Alabama, that sell prescription medicines,

including opioids. At all times relevant to this Complaint, Rite Aid distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Alabama.

314. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined $5 million in civil penalties.

315. In their capacity as wholesale a pharmacy and distributors, Rite Aid and its subsidiaries are National Retail Pharmacy Defendants, and all allegations against the National Retail Pharmacy Defendants herein apply equally to Rite Aid.

316. Walgreens conducts business as a licensed wholesale pharmacy and distributor. At all times relevant to this Complaint, Walgreens distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Alabama.

317. According to a Florida court's Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In certain years, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day.

318. Walgreens has settled opioids-related investigations with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).

319. The Massachusetts Attorney General's Medicaid Fraud Division found that from 2010-15 multiple Walgreens stores across that state failed to monitor the opioid use of some Medicaid patients who were considered high-risk. In 2017, an investigation by the Massachusetts

Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.

320. In their capacity as wholesale pharmacy and distributors, Walgreens and its subsidiaries are National Retail Pharmacy Defendants, and all allegations against the National Retail Pharmacy Defendants herein apply equally to Walgreens.

321. Wal-Mart conducts business as a licensed wholesale pharmacy and distributor. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States, including Alabama.

322. In its capacity as a wholesale pharmacy and distributor, Wal-mart is a National Retail Pharmacy Defendant, and all allegations against the National Retail Pharmacy Defendants herein apply equally to Wal-Mart.

323. Costco failed to track and report suspicious sales of its opioid drugs.

324. Costco could and should have taken action that: (a) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (b) reduced the dispensing of stronger and extended-release opioids; (c) enhanced pharmacist counseling for new opioid patients; (d) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (e) required the use of immediate- release formulations of opioids before extended-release opioids are dispensed.

325. In its capacity as a wholesale pharmacy and distributor, Costco is a National Retail Pharmacy Defendant, and all allegations against the National Retail Pharmacy Defendants herein apply equally to Costco.

326. Having knowledge and/or notice of the damages that the Defendant National

Retail Pharmacies' conduct has caused to Plaintiff and Baby Plaintiff, said Defendants failed to take reasonable care to help curb the damages already incurred, including: (a) donating medication disposal units to community police departments across the country to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to whom the prescription was not written or otherwise diverted or abused; (b) implementing a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients may have; (c) running public education campaigns; (d) limiting to 7 days the supply of opioids dispensed for certain acute prescriptions; (e) reducing the dispensing of stronger and extended-release opioids; (f) enhancing pharmacist counseling for new opioid patients; (g) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (h) requiring the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

327. Defendants could have and should have implemented these reasonable measures and others at any point in the last 20 years. Defendants' failure to exercise reasonable care constitutes negligence, gross negligence, reckless disregard for the rights of the Plaintiff and Baby Plaintiff, rising to a level of outrageous and wanton tortious conduct, and resulting in significant damages to Plaintiff and Baby Plaintiff.

328. The Defendants' unfair and deceptive conduct was well concealed, and only recently uncovered through exhaustive investigation and research. The Defendants deliberately conducted much of their deception through in-person sales visits, in order to avoid generating a potentially discoverable paper trail of their misconduct. The Defendants also concealed from the general public their internal communications about their deceptive course of conduct, including

their plans to hook more patients on higher doses for longer periods and, separately, their knowledge of inappropriate prescribing by high-prescribing doctors that they had targeted to prescribe their opioids.

329. Discovering the nature and extent of the Defendants' unfair and deceptive conduct has been a time-consuming and complex process, further strained by Defendants' lack of cooperation and baseless denials. Due to Defendants' deception, any statutes of limitation otherwise applicable to any claims asserted herein against all Defendants have been tolled by the discovery rule and rules regarding fraudulent concealment.

COUNT I – NEGLIGENCE

330. Plaintiff and Baby Plaintiff reassert the allegations of the foregoing paragraphs as if set forth fully herein.

331. All Defendants owe a non-delegable duty to Plaintiff and Baby Plaintiff to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

332. Defendants had a duty to exercise reasonable care in the marketing, selling, consulting, prescribing, dispensing, and distributing of highly dangerous opioid drugs. Defendants knew or should have known that opioids were unreasonably dangerous and were likely to cause addiction. Defendants owed duties to the Plaintiff and Baby Plaintiff because the injuries alleged herein were foreseeable by the Defendants.

333. A reasonable person could foresee the probability of occurrence of injury to Plaintiff and Baby Plaintiff. Defendants are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of highly dangerous opioid drugs during distribution.

334. Defendants violated Federal law in failing to report suspicious orders of opioid pain medications in the United States. Defendants violated Federal laws in failing to maintain effective controls against the diversion of opioids into other than legitimate medical channels. Defendants also violated Federal laws in failing to operate a system that stop orders which were flagged or should have been flagged as suspicious.

335. Defendants owed a duty to prevent the exposure of Baby Plaintiff to opioids, whether through a prescription to Baby Plaintiff's birth mother or through the existence of the illegal secondary, diversionary market to which Alabama birth mothers had access. As to the diversionary market, the Manufacturer Defendants were required to register with the DEA to manufacture Schedule II Controlled Substances, including the opioids made the subject of this Complaint. See 21 U.S.C. § 823(a). The purpose of registration is the "maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes." 21 U.S.C. § 823(a)(1). Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances under a strict process prescribed under Federal law. See e.g., 21 C.F.R. § 1301.74; 21 C.F.R. § 1300.02; 21 C.F.R. § 1300.01.

336. Similarly, and of equal importance, each Distributor and Pharmacy Defendant was also required to register with the DEA, pursuant to the federal Controlled Substance Act. See 21 U.S.C. § 823(b) and (e); 28 C.F.R. § 0.100. Each Distributor and Pharmacy Defendant is a

"registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Federal law requires that Distributors, including Pharmacy distributors, of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, research, or industrial channels." 21 U.S.C. § 823(b)(1). As with the Manufacturer Defendants, federal regulations impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). In addition to reporting all suspicious orders, Distributor Defendants must also *affirmatively stop shipment on any order which is flagged as suspicious* and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. Regardless, all flagged orders must be reported.

337. Defendants' breach of each of the aforementioned duties resulted in a foreseeable harm to Plaintiff.

338. The aforementioned conduct of Defendants proximately caused damage to the Plaintiff and Baby Plaintiff.

339. Defendants have failed to diligently respond to suspicious orders in contravention of Federal law.

340. Defendants have failed to provide effective controls and procedures to guard against the diversion of controlled substances in contravention of Federal law.

341. Defendants have willfully turned a blind eye towards the actual facts by regularly distributing large quantities of controlled substances to retailers and dispensers who are serving a customer base substantially comprised of individuals who are abusing and/or diverting prescription medications, many of whom are addicted and all of whom can reasonably be expected to become addicted. Defendants negligently acted with others by dispensing controlled substances for illegitimate medical purposes, operating bogus pain clinics that do little more than provide prescriptions for controlled substances, thereby creating and continuing addictions to prescription medications in this state.

342. Defendants have, by their acts and omissions, proximately caused and substantially contributed to damages to Plaintiff and Baby Plaintiff by violating Federal law, by creating conditions which contribute to violations of Federal laws by others, and by their negligent and/or reckless disregard of the customs, standards, and practices within their own industries.

343. Plaintiff and Baby Plaintiff have suffered and will continue to suffer enormous damages as the proximate result of the failure by Defendants to comply with Federal law.

344. Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties. Plaintiff and and Baby Plaintiff are within the class of persons the Federal laws were intended to protect.

345. The harm that has occurred is the type of harm that the Federal laws were intended to guard against.

346. Alternatively, to the extent that Defendants' statutory violations do not obviate the

need to show breaches of the duty of care, each Defendant breached its aforesaid duties of care.

347. There is no social value to Defendants' challenged behavior. In fact, Defendants' entire conduct, behavior, actions, misrepresentations, conspiracies, and omissions are against Federal law.

348. On the other hand, there is immense social value to the interests threatened by Defendants' behavior, namely the health, safety, and welfare of Plaintiff and Baby Plaintiff.

349. Defendants' conduct fell below the reasonable standard of care and was negligent. Their negligent acts include:

a. Consciously supplying the market in the United States with highly-addictive prescription opioids, including misrepresenting, understanding, or obfuscating the highly addictive propensities of opioid pills;

b. Using unsafe marketing, labeling, distribution, and dispensing practices, including failing to warn or advise physicians to conduct an addiction family history of each and every potential patient;

c. Affirmatively enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;

d. Failing to properly train or investigate their employees;

e. Failing to properly review and analyze prescription orders and data for red flags;

f. Failing to report suspicious orders or refuse to fill them;

g. Failing to provide effective controls and procedures to detect and/or guard against theft and diversion of controlled substances;

h. Failing to police the integrity of their supply chains; and

i. Creating misleading information with the intention of having prescribing physicians rely upon it.

350. Each Defendant had an ability to control the opioids at a time when it knew or should have known it was passing control of the opioids to an actor further down in the supply chain that was incompetent or acting illegally and should not be entrusted with the opioids.

351. Defendants sold prescription opioids in the supply chain knowing (a) there was a substantial likelihood many of the sales were for non-medical purposes and, (b) opioids are an inherently dangerous product when used for non-medical purposes, and (c) that every patient, before being prescribed even one opioid pill, needed to have a complete family history of addiction to alcohol and drugs, with any such history as a contraindication of any opioid use.

352. Defendants were negligent or reckless in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent or ameliorate such distinctive and significant dangers.

353. Controlled substances are dangerous commodities. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their business.

354. Defendants were also negligent or reckless in failing to guard against foreseeable third-party misconduct, e.g., the foreseeable conduct of: corrupt prescribers, corrupt pharmacists and staff, and/or criminals who buy and sell opioids for non-medical purposes.

355. Defendants are in a limited class of registrants authorized to legally distribute controlled substances. This places Defendants in a position of great trust and responsibility vis-a-vis Plaintiff and Baby Plaintiff. Defendants owe a special duty to Plaintiff and Baby Plaintiff. That duty cannot be delegated to another party.

356. Plaintiff and Baby Plaintiff are without fault, and the injuries to Plaintiff and Baby Plaintiff would not have happened in the ordinary course of events if the Defendants used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

357. The aforementioned conduct of Defendants proximately caused damage to

Plaintiff and Baby Plaintiff.

358. As a proximate result of Defendants' conduct, Defendants have caused Plaintiff and Baby Plaintiff's injuries related to the diagnosis and treatment of opioid-related conditions. Plaintiff and Baby Plaintiff have incurred massive costs by providing uncompensated care as a result of opioid-related conditions.

359. The injuries to Plaintiff and Baby Plaintiff would not have happened in the ordinary course of events had Defendants exercised the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business in the distribution of opioids.

360. Plaintiff and Baby Plaintiff are entitled to recover damages as a result of Defendants' negligence, in an amount to be determined at trial.

COUNT II – NEGLIGENCE *PER SE*

361. Plaintiff and Baby Plaintiff reassert the allegations of the foregoing paragraphs as if set forth fully herein.

362. Defendants owed non-delegable statutory duties to Plaintiff and Baby Plaintiff. These duties were established to prevent the specific type of harm of which Plaintiff and Baby Plaintiff suffered. Defendants had a duty to prevent the diversion of the drugs which harmed Plaintiff and Baby Plaintiff. The Manufacturer Defendants were required to register with the DEA to manufacture Schedule II Controlled Substances, including the opioids made the subject of this Complaint. See 21 U.S.C. § 823(a). The purpose of registration is the "maintenance of *effective controls against diversion* of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such

controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes. 21 USCA § 823(a)(1) (emphasis added). Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances via a process defined by Federal laws and regulations.

363. Similarly, and of equal importance, each Distributor and Pharmacy Defendant was also required to register with the DEA, pursuant to the federal Controlled Substance Act. See 21 U.S.C. § 823(b) and (e); 28 C.F.R. § 0.100. Each Distributor and Pharmacy Defendant is a "registrant" as a distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). As with the Manufacturer Defendants, federal regulations impose a non-delegable duty upon distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

364. In addition to reporting all suspicious orders, Distributor Defendants must also *affirmatively stop shipment on any order which is flagged as suspicious* and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor

can determine that the order is not likely to be diverted into illegal channels. Regardless, all flagged orders must be reported.

365. The harm caused to Plaintiff and Baby Plaintiff were a direct and foreseeable result of Defendants' breach of their statutory duties.

COUNT III – NUISANCE

366. Plaintiff and Baby Plaintiff reassert the allegations of the foregoing paragraphs as if set forth fully herein.

367. Under Alabama Law, a nuisance "is anything that works hurt, inconvenience, or damage to another." Ala. Code § 6-5-120. "A public nuisance is one which damages all persons who come within the sphere of its operation, though it may vary its effects on individuals." Ala. Code § 6-5-121.

368. The nuisance is the over-saturation of opioids in Alabama creating the Opioid Crisis and the adverse social, economic, and human health outcomes associated with widespread opioid use, which led to the increasing incidence of NAS.

369. All Defendants substantially participated in public nuisance-causing activities.

370. Each Defendant's conduct, both individually and collectively, in creating and then maintaining the opioid crisis constitutes a public nuisance. The conduct of each Defendant involves a significant interference with the public health, the public safety, the public peace, and the public comfort. Each Defendant's conduct giving rise to the opioid crisis is of a continuing nature and has produced a permanent or long-lasting effect that, as each Defendant knows or has reason to know, has a significant effect on the entire community of Alabama.

371. Defendants' public nuisance-causing activities include selling or facilitating the excessive sale of prescription opioids to the patients and citizens of Alabama, as well as to

unintended users, including newborns and children, pregnant women, and potential mothers.

372. Defendants' public nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

373. Defendants' knew and should have known that its promotion of opioids was false and misleading and that its deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of the public nuisance—the opioid epidemic

374. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used and a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

375. Defendants' activities unreasonably interfered with the rights of Plaintiff and Baby Plaintiff.

376. The Defendants' interference with these rights of Plaintiff and Baby Plaintiff is unreasonable because said wrongful conduct:

a. Has harmed and will continue to harm NAS-affected children;

b. Is proscribed by Alabama statutes and regulation, including the consumer protection statute;

c. Is of a continuing nature and it has produced long-lasting effects; and

d. Defendants have reason to know their conduct has a significant effect upon Plaintiff and Baby Plaintiff.

377. The public nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within families and entire communities and in the shattering of the life of Plaintiff and Baby Plaintiff.

378. The resources of the communities of the Plaintiff and Baby Plaintiff are insufficient to deal with needs created by the Opioid Crisis, and these limited resources are being unreasonably consumed in efforts to address the Crisis, including efforts to address the overwhelming number of children born with NAS.

379. Defendants' public nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest Defendants dissemination of false "scientific" facts, physician advice, and information.

380. At all times, all Defendants possessed the right and ability to control the nuisance causing outflow of opioids from pharmacy locations or other points of sale. Manufacturer Defendants flooded the distribution channels and the geographic and demographic area of Alabama with opioid pills. Distributor Defendants had the power to shut off the supply of illicit opioids to patients and consumers of Alabama, yet they did the opposite by flooding Alabama with opioid pills. National Retail Pharmacy Defendants could have refused to fill suspicious prescriptions.

381. Plaintiff and Baby Plaintiff also have suffered unique harms and special damages different from the public at large, namely, that they personally suffered NAS.

382. As a direct and proximate result of the public nuisance, Plaintiff and Baby Plaintiff have incurred special legal damage, born a great burden and suffered the irreparable

harm of living with increased risk of serious latent disease.

383. The effects of the nuisance can be abated, and the further occurrence of such harm can be prevented. All Defendants share in the responsibility for doing so.

384. The acts forming the basis for the nuisance claim against Defendants were wanton, malicious, and/or attended with circumstances of aggravation.

385. Therefore, Plaintiff and Baby Plaintiff demands judgment in their favor against the Defendants for injunctive relief, abatement of the public nuisance, and for damages in an amount to be determined by a jury, together with all cost of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT IV – UNJUST ENRICHMENT

386. Plaintiff and Baby Plaintiff repeats, realleges, and incorporates by reference all other paragraphs of this Complaint, as if fully set forth herein.

387. This claim is brought under the Alabama common law of unjust enrichment.

388. The Plaintiff and Baby Plaintiff have provided services for themselves or family members with opioid-related conditions that Defendants are responsible for creating. Plaintiff and Baby Plaintiff thereby conferred a benefit on Defendants because Defendants should bear the expense of treating the Plaintiff and Baby Plaintiff's opioid conditions. This is because Defendants created the opioid epidemic and Baby Plaintiff's opioid conditions, as described in this Complaint.

389. Defendants appreciated and knew of this benefit because they knew their opioid distribution policies would cause, and in fact, have caused, the Plaintiff and Baby Plaintiff to provide services to Plaintiff and Baby Plaintiff with opioid-related conditions that Defendants

were responsible for creating.

390. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the opioid epidemic.

391. Defendants have received and continue to receive the benefit of the false, deceptive, and unfair distribution of their opioid products directly to the Plaintiff and/or Baby Plaintiff.

392. The circumstances under which Defendants accepted or retained the benefit, described above, were such as to make it inequitable for Defendants to retain the benefit without payment of its value.

393. As described above, the benefit was received and retained under such circumstances that it would be inequitable and unconscionable to permit Defendants to avoid payment therefore.

394. Defendants have therefore been unjustly enriched at the expense of Plaintiff and Baby Plaintiff.

395. By reason of the foregoing, Defendants must disgorge their unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and provide restitution to the Plaintiff and Baby Plaintiff.

COUNT V – FRAUD AND DECEIT

396. Plaintiff and Baby Plaintiff repeats, realleges, and incorporates by reference all other paragraphs of this Complaint, as if fully set forth herein.

397. This claim is brought under the Alabama common law of fraud and deceit.

398. As alleged herein, Defendants violated their duty not to actively deceive by intentionally and unlawfully making knowingly false statements, and by intentionally and unlawfully omitting and/or

concealing information.

399. Defendants made misrepresentations and failed to disclose material facts to the Plaintiff and Baby Plaintiff in order for Baby Plaintiff's mother to purchase and consume opioids as set forth herein.

400. Defendants, individually and acting through their employees and agents, and in concert with each other, were knowingly deceptive during the relevant period, and their deceptions were intended to induce reliance. These deceptions include but are not limited to:

a. Acknowledgment of the Distributor Defendants by and through their front group, the HDMA, that distributors are at the center of a sophisticated supply chain and therefore, are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers;

b. Acknowledgment of the Distributor Defendants that because of their unique position within the "closed" system, they were to act as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market;

c. Cardinal Health claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse;

d. AmerisourceBergen took the same position as its counterpart within the industry and stated that it was "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare to help find solutions that will support appropriate access while limiting misuse of controlled substances;"

e. More holistically, Defendants misrepresented that not only do its members have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs but undertake such efforts as responsible members of society; and

f. Such other omissions or concealments as described above in this Complaint.

401. Defendants also created and/or disseminated advertisements, scientific studies, and patient and prescriber education materials that contained false, misleading, and untrue

statements concerning the ability of opioids to improve function long-term.

402. Defendants created and/or disseminated advertisements, scientific studies, and patient and prescriber education materials that contained false, misleading, and untrue statements concerning the ability of opioids to improve quality of life while concealing contrary data.

403. Defendants created and/or disseminated advertisements, scientific studies, CMEs, and patient and prescriber education materials that contained false, misleading, and untrue statements concerning the evidence supporting the efficacy of opioids long-term for the treatment

of chronic non-cancer pain, including known rates of abuse and addiction and lack of validation for long-term efficacy.

404. Defendants disseminated misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction, even for high- risk patients.

405. Defendants disseminated misleading statements concealing the true risk of addiction in the elderly.

406. Defendants endorsed, directly distributed, and assisted in the distribution of publications that presented an imbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs.

407. Defendants falsely claimed that withdrawal is simply managed.

408. Defendants misrepresented that increased doses of opioids pose no significant additional risks.

409. By engaging in the acts and practices alleged herein, Defendants, in the relevant time period and with the intent that others rely on their omissions or suppression of information, omitted material facts that Defendants had a duty to disclose by virtue of these Defendants' other

representations, including but not limited to:

a. There being no legitimate medical purpose for the copious amounts of opioids shipped into and around Plaintiff' communities;

b. That they failed to report to the DEA suspicious orders;

c. That they failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical scientific and industrial channels by sales to certain customers;

d. That they failed to prevent against diversion from legitimate to non-legitimate channels;

e. That they failed to conduct meaningful due diligence to ensure that controlled substances were not diverted into other than legitimate channels;

f. That they failed to keep and maintain accurate records of Schedule II – V controlled substances; and

g. Such other omissions or concealments as alleged above in this Complaint.

410. Defendants intended and had reason to expect under the operative circumstances that the Plaintiff and Baby Plaintiff would be deceived by Defendants' statements, concealments, and conduct as alleged herein and that Plaintiff and Baby Plaintiff would act or fail to act in reasonable reliance thereon.

411. Defendants intended that the Plaintiff and Baby Plaintiff would rely on these Defendants' misrepresentations and omissions; Defendants intended and knew that this reasonable and rightful reliance would be induced by these Defendants' misrepresentations and omissions; and, Defendants intended and knew that such reliance would cause Plaintiff and Baby Plaintiff to suffer loss.

412. Plaintiff and Baby Plaintiff rightfully, reasonably, and justifiably relied on

Defendants' representations and/or concealments, both directly and indirectly. As the Defendants knew or should have known, the Plaintiff and Baby Plaintiff were directly and proximately injured as a result of this reliance, Plaintiff and Baby Plaintiff injuries were directly and proximately caused by this reliance.

413. Defendants' false representations and omissions were material and were made and omitted intentionally and recklessly.

414. Defendants' misconduct alleged, in this case, is ongoing and persistent.

415. Defendants' misconduct alleged, in this case, does not concern a discrete event or discrete emergency of the sort Plaintiff would reasonably expect to occur and is not part of the normal and expected costs of a family member, mother, father, or child. Plaintiff alleges wrongful acts which are neither discrete nor of the sort Plaintiff and Baby Plaintiff can reasonably expect.

416. Plaintiff and Baby Plaintiff have incurred expenditures over and above that which is customary for the Plaintiff and Baby Plaintiff.

417. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

418. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

419. Plaintiff and Baby Plaintiff have suffered monetary damages as aforesaid. As such Plaintiff and Baby Plaintiff seek all legal and equitable relief as allowed by law, including inter alia injunctive relief, restitution, disgorgement of profits, compensatory, and punitive damages under Ala. Code § 6-11-20, and all damages allowed by law to be paid by the Defendants, as well

as attorney fees, and costs, and pre- and post-judgment interest.

COUNT VI - WANTONNES

420. Plaintiff and Baby Plaintiff repeats, realleges, and incorporates by reference all other paragraphs of this Complaint, as if fully set forth herein.

421. This cause of action is brought under Alabama common law relating to wantonness.

422. All Defendants carried out conduct with a reckless or conscious disregard of the rights or safety of others, including Plaintiff and Baby Plaintiff.

423. The actions and failure to act of the Defendants enumerated in this Complaint were made consciously and with reckless disregard of the rights and safety of others and Defendants were aware that harm would likely or probably result from their actions or failure to act.

424. As a direct and proximate result of Defendants' wantonness, Plaintiff and Baby Plaintiff have suffered and continue to suffer injury-in-fact and actual damages.

425. As a proximate result of Defendants' wantonness, Defendants have caused Plaintiff and Baby Plaintiff injuries related to the treatment of opioid-related conditions. Plaintiff and Baby Plaintiff have incurred massive costs by providing uncompensated care as a result of opioid-related conditions.

426. As a result of the Defendants' wantonness, Plaintiff and Baby Plaintiff are entitled to compensatory and punitive damages, in an amount to be determined at trial.

COUNT VII – ALABAMA DECEPTIVE TRADE PRACTICES ACT

427. Plaintiff and Baby Plaintiff realleges and incorporates by reference all paragraphs above.

428. Defendants violated the Alabama Deceptive Trade Practices Act, Ala. Code § 18-19-1, et seq. ("ADTPA") by engaging in unfair and deceptive acts or practices and/or unconscionable consumer sales acts and practices in the state of Alabama.

429. This Cause of Action is brought in the public interest under the ADTPA and seeks a declaratory judgment that Defendants have violated the ADTPA, an injunction enjoining Defendants' misrepresentations and other misconduct described in this Complaint, civil penalties, and restitution to Plaintiff and Baby Plaintiff. The ADTPA prohibits, in connection with consumer transactions, unfair, deceptive or unconscionable consumer sales practices that mislead consumers about the nature of the product they are receiving. The ADTPA prohibits sellers from representing that the subject of a consumer transaction has sponsorship, approval, performance characteristics, accessories, uses, or benefits that it does not have.

430. The following acts are deemed to be deceptive under Alabama law:

i. Making any express or implied statement in connection with the marketing or advertisement of any product that is false, or has the capacity, tendency or effect of deceiving or misleading consumers; or omitting any material information such that the express or implied statement deceives or tends to deceive consumers.

ii. Making any representation, in connection with the marketing or advertising of a product, about research that has been performed, including but not limited to, any representation that a product has been clinically tested unless at the time the claim is made, competent and reliable scientific evidence exists substantiating such claim.

iii. Making in connection with the marketing or advertising of a product any . . . statements or representations concerning a product that materially contradict or conflict with any other statements or representations the Defendants made about such Product and rend such statements or representations misleading and/or deceptive.

iv. Making, or causing to be made, any written or oral claim that is false, misleading or deceptive.

v. Representing that any product has any sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.

vi. Representing that any product has any sponsorship, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.

vii. Making in a promotional context an express or implied representation, not approved or permitted for use in the labeling or under the FDCA, that a product is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by competent and reliable scientific evidence, whether or not such express or implied representation is made by comparison with another drug or treatment, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, a quotation, or another reference.

431. As alleged herein, each Defendant, at all times relevant to this Complaint, violated the ADTPA by making deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

432. Plaintiff and Baby Plaintiff have suffered monetary damages as aforesaid. As such, Plaintiff and Baby Plaintiff seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory, and punitive damages under Ala. Code § 6-11-20, and all damages allowed by law to be paid by Defendants, as well as attorneys' fees, costs, and pre-judgment interest.

COUNT VIII – CIVIL CONSPIRACY

433. Plaintiff and Baby Plaintiff reassert the allegations in the foregoing paragraphs as if fully set out herein.

434. All Defendants acted in concert to mislead medical professionals, patients, the scientific community, and the general public about the addictive nature of opioids and the risk of

serious latent disease associated with *in utero* exposure to opioids so that their profits would increase.

435. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids and/or distribution of opioids into Alabama.

436. The Manufacturer Defendants continuously supplied prescription opioids to the Distributor Defendants despite having actual or constructive knowledge that said Distributors were habitually breaching their common law duties. The Distributor Defendants continuously supplied prescription opioids to pharmacies despite having actual or constructive knowledge that said pharmacies were habitually breaching their common law duties.

437. Without the Distributor Defendants' supply of prescription opioids, National Retail Pharmacies would not be able to fill and dispense the increasing number of prescription opioids throughout Alabama.

438. Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

439. No Defendant in this opioid network would have succeeded in profiting so significantly from the opioid epidemic without the concerted conduct of the other party, and none would have succeeded so significantly without engaging in the wrongful conduct as herein alleged.

440. The Manufacturer Defendants likewise benefitted from this distribution conspiracy in that the more pervasive opioid diversion became, the more the Manufacturer Defendants profited. Despite access to the same information in the hands of the Distributor Defendants, the Manufacturer Defendants ignored the warning signs of opioid diversion.

441. As a result of the concerted actions between and among the Defendants, Plaintiff

and Baby Plaintiff have suffered damages.

COUNT IX – PRODUCTS LIABILITY

442. Plaintiff and Baby Plaintiff reassert the allegations in the foregoing paragraphs as if fully set out herein.

443. At all times material to this action, Defendants were engaged in the business of the design, development, manufacture, testing, packaging, promotion, marketing, distribution, labeling, and/or sale of opioid products.

444. At all times material to this action, Defendants' opioid products were expected to reach, and did reach, consumers in the State of Alabama, and Plaintiff and Baby Plaintiff herein, without substantial change in the condition in which they were sold.

445. Defendants knew that the damage causing characteristics of Defendants' product include its addictive properties on potential mothers and its in utero impacts on their future children.

446. Defendants knew that prolonged use of opioids leads to decrease effectiveness, requiring increases in doses to achieve the same level of pain relief, markedly increasing the risk of significant side effects and addiction. Defendants conducted studies documenting these risks, yet failed to publish the results or warn of the documented risks.

447. The risks of opioid addiction and the risk to children in utero are grave and Defendants had a duty to warn about these risks.

448. Providing such warnings would have been easily feasible, but would have interfered with Defendants' marketing efforts. Instead, Defendants' engaged in a multimillion dollar marketing and advertising effort promoting falsehoods and minimizing the risk of addiction and withdrawal from long term opioid use.

449. Defendants knew that opioids are too addictive and too debilitating for long-term use for chronic pain, barring exceptional circumstances. Defendants knew that the only safe uses for their product were end of life care, short term pain relief after surgery, and pain relief related to cancer. Defendants failed to warn Alabama physicians, potential mothers and pregnant women of the dangers of using their product outside of these areas.

450. Defendants' products were unreasonably dangerous at the time they left the control of Defendants because of inadequate warning.

451. Because of Defendants' knowledge of the risks to mothers and their neonatal children, and their extensive efforts to obscure these risks, Defendants are liable for all resulting damages caused to Plaintiff and Baby Plaintiff.

452. The opioid product manufactured and/or supplied by Defendants were defective in design in that an alternative design exists that would prevent addiction, NAS and severe and permanent injury to pregnant women and their unborn children.

453. A reasonably prudent manufacturer or seller would not have put Defendants' products on the market had it known of the products' dangerous condition and/or defective design.

454. Defendants designed their product in such a way that it could easily be abused by crushing of pills with the resulting powder ingested by inhalation or injection.

455. Defendants were aware that their products were being abused in this manner on a large scale, making this a reasonably anticipated use.

456. Despite this knowledge, Defendants only recently altered the design of their product to be "enteric," that is, changed it to a form that prevented such crushing and consumption. This change was only made after years of public and legal pressure.

457. Defendants promoted their unreasonably dangerous design by actively undercutting the prescription alternative nonsteroidal ani-inflammatory drugs, pushing the misinformation that such non-opioid drugs were not effective for the treatment of long-term pain.

458. Thus, Defendants are liable for the damages caused to Plaintiff and Baby Plaintiff by their opioid products' unreasonably dangerous and defective design and inadequate warnings of their opioids' addictive properties.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff and Baby Plaintiff, Darlene Mathieu, individually and as next of friend and guardian of Baby M.V.M., request that the Court grant the following relief:

a. Hold a jury trial and enter judgment against Defendants, jointly and severally, and in favor of Plaintiff and Baby Plaintiff;

b. Award compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff and Baby Plaintiff for all damages; punitive damages; pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate; and such equitable relief against Defendants as the Court should find appropriate, including individual compensatory and punitive damages for personal injury, medical costs, pain and suffering, treatment, future treatment costs, lost wages and all other legal damages to be determined by follow-on proceedings, injunctive relief, abatement, and other orders;

c. Award Plaintiff and Baby Plaintiff costs of suit; including reasonable attorneys' fees as provided by law;

d. Award such further and additional relief as the Court may deem just and proper under the circumstances.

e. Plaintiff and Baby Plaintiff seek a trial by jury for all counts so triable.

DATED: January 8, 2024.

Respectfully Submitted,

/s/ T Roe Frazer II
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